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# FY 2010 ORA FIELD WORKPLAN



**DEPT OF HEALTH & HUMAN SERVICES  
FOOD & DRUG ADMINISTRATION  
PROGRAM PLANNING & WORKFORCE  
MANAGEMENT BRANCH  
ORA/ORM/DPEM**



**Memorandum**

Date September 23, 2009

From Director, Program Planning and Workforce Management Branch

Subject Final FY 2010 ORA Field Workplan

To Regional Food and Drug Directors  
District Directors  
Regional Laboratory Directors: Northeast, Southeast, Arkansas, Pacific Northwest, Pacific Southwest, WEAC, and FCC  
Investigations Branch Directors  
Laboratory Branch Directors

The enclosed Final FY 2010 ORA Field Workplan is based on the Center's compliance program forecasts and incorporates input of the Centers and the Field Committees during their review of the draft Workplanning Sheets. The FY 2010 Workplan is based on ORA's planning level of 1,963 Operational FTEs. This represents an overall increase of 90 Operational FTEs from the FY 2009 Workplan.

A significant addition to the FY 2010 Workplan includes resources to meet Congressional Targets. These Targets are linked to the level of appropriations in the Congressional budget. ORA's appropriated funding increased and Congress directed a specific corresponding increase in operational activities. These increases are directed towards foreign inspections, domestic inspections, import field exams, and sample collection/analyses. The FY 2010 Workplan provides sufficient resources to meet both the Congressional Targets and Performance Goals. Please see below for a listing by program area of the significant planning measures that are included in the FY 2010 Workplan:

**Foods and Cosmetics:**

- 140,200 Import Field Exams
- 4,100 Domestic Food Safety Inspections
- 600 Foreign Food Inspections, with 400 planned in HQ

**Biologics:**

- 543 Domestic Tissue Inspections
- 13 Foreign Tissue Inspections

### **Human Drugs:**

- 6,200 Import Field Exams
- 942 Foreign Human Drug Inspections, with 253 in HQ
- 2,535 Human Drug Domestic Inspections
- 203 Import Sample Collection/Analyses under 52832 and 202 Import Sample Collection/Analyses under 56008H

### **Animal Drugs & Feeds:**

- 3500 Import Feed Field Exams
- 100 Import Animal Drug Field Exams
- 8 Foreign Feed Inspection
- 62 Foreign Animal Drug Inspections
- 205 Domestic Animal Drug Inspections

### **Devices and Radiological Health:**

- 13,180 Import Field Exams
- 354 Foreign Medical Device Inspections
- 2025 Medical Device Domestic Inspections

As in the FY 2009 Workplan, the FY 2010 Workplan places a greater emphasis on a risk based approach to food Workplanning. Districts will have specific lists of high risk firms to inspect, based on risk modeling by CFSAN. While it is difficult to plan for inspection of the high risk firms on a program by program basis, overall each District has sufficient planned inspectional resources and state contracts to cover all their high risk food firms. For a District, it means you may overburn in the Domestic Cheese Program, and underburn in the Domestic Food Safety Program, but overall the resources should balance out.

The "FY 2010 Workplan Changes" spreadsheets provide a listing of programs compared to the FY 2009 ORA Field Workplan, and will enable you to identify where specific resource shifts and programmatic cuts occurred.

The FY 2010 Servicing Laboratories Table continues to reflect the laboratory servicing changes consistent with ORA's Laboratory capabilities determined by the Division of Field Science. **Please review this table carefully before shipping any samples and note the latest changes.**

The FY 2010 Workplan has been published to a CD format. Your CD is non-writable and cannot be used to store or save data; however you may save any of the files to your PC system or to another media, i.e., zip drive, diskette, etc. You may make and distribute as many copies of this CD as needed. For further instructions, consult 'A User's Guide – READ ME FIRST' located on the CD. If you have any technical questions, please e-mail Anita McCurdy at [Anita.McCurdy@fda.hhs.gov](mailto:Anita.McCurdy@fda.hhs.gov).

Any questions about the attachments or programs in the Field Workplan should be addressed to the program/project's planning analyst identified on the workplanning sheets (Form FDA 2622). Policy concerns should be directed to Carrie Mampilly at (301) 796-4390.

A handwritten signature in black ink, appearing to read "Carrie M. Mampilly". The signature is fluid and cursive, with the first name "Carrie" and last name "Mampilly" clearly distinguishable.

Carrie M. Mampilly

Attachments- See "FY 2010 Workplan Changes" files

# FOODS AND COSMETICS

## FY 2010 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENTS	WORKPLAN FTEs FY 2009	WORKPLAN FTEs FY 2010	FTE DIFFERENCE
03003,A	Import Acidified and Low Acid Canned Foods	18.0	19.8	1.8
03037,D	Domestic and Imported Cheese and Cheese Products	28.6	22.2	-6.4
03803A	Domestic Acidified and Low Acid Canned Food	18.0	13.9	-4.1
03803,B	Domestic Food Safety	139.7	107.2	-32.5
03819A,B	Import Foods - General	247.1	246.4	-0.7
03842,B	Domestic Fish and Fishery Products Inspections	65.0	44.1	-20.9
03844,B	Import Seafood Products	84.7	91.7	7.0
03847H	Juice HACCP Inspection Program	6.9	7.7	0.8
03R233	Unspecified Foreign Inspections/Assessments	7.3	1.6	-5.7
03F098	Imported/Domestic Micro Assignment	48.9	48.9	
03F830	CFSAN Environmental Sampling Assignments		61.1	
03R839	Outbreak and Emergency Response		51.2	
03R843	Contract Management	12.0	12.0	
03R845	Food Defense	38.0	28.0	-10.0
03R816	Methods Validation/Development Program	10.0	10.0	
<b>03</b>	<b>Foodborne Biological Hazards</b>	<b>724.2</b>	<b>765.8</b>	<b>41.6</b>
04004A,D	Pesticides & Industrial Chemicals in Domestic & Import Food	59.7	59.5	-0.2
04018	Seafood Chemotherapeutics Sampling	32.6	33.0	0.4
04019A,B,C	Toxic Elements in Foods & Foodware (Domestic & Import)	17.0	19.2	2.2
04839	Total Diet Study	28.6	28.6	
04F800	Field Assignments for Chemical Contaminants	6.4	6.5	0.1
04R816	Methods Validation/Development Program	10.6	10.6	
04R838	Forensic Evaluation and Sample Analysis	12.0	12.0	0.0
04R839	Outbreak and Emergency Response		11.9	
<b>04</b>	<b>Pesticides and Chemical Contaminants</b>	<b>166.9</b>	<b>181.3</b>	<b>14.4</b>
07001	Mycotoxins in Domestic and Imported Foods	14.6	14.6	
07R816	Methods Validation/Development Program	4.5	4.5	
<b>07</b>	<b>Molecular Biology and Natural Toxins</b>	<b>19.1</b>	<b>19.1</b>	
09006A,B	Imported Foods-Food and Color Additives	13.6	14.6	1.0
<b>09</b>	<b>Food and Color Additives Petition Review</b>	<b>13.6</b>	<b>14.6</b>	<b>1.0</b>
18002	Retail Food Protection- State Program	24.0	26.0	2.0
18003	Milk Safety Program	20.4	20.4	
18004	Molluscan Shellfish Evaluation Program	14.5	14.7	0.2
18029A-F	Interstate Travel Program Conveyances & Support Facilities	21.8	21.8	
<b>18</b>	<b>Technical Assistance: Food &amp; Cosmetics</b>	<b>80.7</b>	<b>82.9</b>	<b>2.2</b>
21002	Medical Foods - Domestic and Import	4.3	3.7	-0.6
21003	Domestic Food Labeling and Economics Program	3.1	3.1	
21005	Domestic & Import NLEA	11.4	12.6	1.2
21006	Infant Formula Program	5.4	5.6	0.2
21008	Dietary Supplements	20.3	22.2	1.9
21839	Selected Nutrients in Foods - Total Diet	3.4	3.4	
21R816	Methods Validation/Development Program	1.5	1.5	
<b>21</b>	<b>Food Composition, Standards, Labeling, &amp; Econ</b>	<b>49.4</b>	<b>52.1</b>	<b>2.7</b>
29001	Cosmetics Program - Imported and Domestic	8.1	7.6	-0.5
<b>29</b>	<b>Colors and Cosmetics Technology</b>	<b>8.1</b>	<b>7.6</b>	<b>-0.5</b>
	<b>Total Mission Direct: Pre and Annual Planned FTEs</b>	<b>1062.0</b>	<b>1123.4</b>	<b>61.4</b>

# BIOLOGICS

## FY 2010 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENT	WORKPLAN FTEs FY 2009	WORKPLAN FTEs FY 2010	FTE DIFFERENCE
41002	Tissue Establishments	22.5	25.5	3.0
41808	Good Laboratory Practices	*	*	
41809	Institutional Review Board	*	*	
41810	Sponsors, CROs, Monitors	*	*	
41811	Clinical Investigators	4.4	4.4	
<b>41</b>	<b>Human Cellular, Tissue, &amp; Gene Therapies</b>	<b>26.9</b>	<b>29.9</b>	<b>3.0</b>
42001F,G	Blood Banks	53.0	53.5	0.5
42002	Source Plasma Establishments	10.4	10.9	0.5
42007	Exam of Blood/Components - Import	3.0	3.5	0.5
42008,A	Licensed Viral Marker Test Kits	2.5	2.5	
42809	Institutional Review Board	*	*	
42810	Sponsors, CROs, Monitors	*	*	
42811	Clinical Investigators	4.0	4.0	
42811	Foreign BIMO Inspection	**	**	
42845A,B,C	Medical Device Manufacturers (Biologics)	0.5	0.5	
42848A,F,G	Plasma Derivatives of Human Origin	3.0	3.0	
<b>42</b>	<b>Blood &amp; Blood Products</b>	<b>76.4</b>	<b>77.9</b>	<b>1.5</b>
45809	Institutional Review Board	*	*	
45810	Sponsors, CROs, Monitors	*	*	
45811	Clinical Investigators	6.5	7.0	0.5
45848A,F,G	Licensed Allergenic Products	0.7	0.7	
45848B,C,D	Vaccine Products	4.5	5.5	1.0
<b>45</b>	<b>Vaccines &amp; Allergenic Products</b>	<b>11.7</b>	<b>13.2</b>	<b>1.5</b>
	<b>Total Mission Direct: Pre and Annual Planned FTEs</b>	<b>115.0</b>	<b>121.0</b>	<b>6.0</b>

\* BIMO: 41808, 41809, and 41810 are planned under 41811; 42809 & 42810 are planned under 42811; 45809 & 45810 are planned under 45811.

\*\* Foreign BIMO Inspections include GLPs and Clinical Investigators in PPS 41, 42, & 45 and are planned under 42811.

# HUMAN DRUGS

## FY 2010 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENTS	WORKPLAN FTEs FY 2009	WORKPLAN FTEs FY 2010	FTE DIFFERENCE
46832B,C	NDA Pre-Approval Inspections/Investigations (Domestic)	9.0	9.5	0.5
46832B,C	NDA Pre-Approval Inspections/Investigations (Foreign)	14.0	13.0	-1.0
46832M	Pre-License Biotech (BLA) Inspections/Investigations (DOM/FOR)		2.0	
<b>46</b>	<b>New Drug Evaluation</b>	<b>23.0</b>	<b>24.5</b>	<b>1.5</b>
48001/A	In Vivo Bioequivalence (Domestic)	5.5	4.5	-1.0
48001/A	Foreign Inspections (In Vivo, GLP, CI)	3.5	3.5	
48808	Good Laboratory Practices	4.0	2.0	-2.0
48809	Institutional Review Boards	5.8	6.8	1.0
48810	Sponsors, Contract Research Orgs, Monitors	3.3	4.3	1.0
48811	Clinical Investigators (Domestic)	25.0	28.1	3.1
48811	Clinical Investigators (Foreign)	15.0	16.0	1.0
<b>48</b>	<b>Bioresearch Monitoring</b>	<b>62.1</b>	<b>65.2</b>	<b>3.1</b>
52832,B,C	ANDA Pre-Approval Inspections/Investigations (Domestic)	5.0	5.0	
52832,B,C,E	ANDA Pre-Approval Inspections/Investigations (Foreign)	10.0	10.0	
<b>52</b>	<b>Generic Drug Evaluation</b>	<b>15.0</b>	<b>15.0</b>	
53001A,B	Adverse Drug. Exp. Rpt. Regul (Domestic)	10.0	8.0	-2.0
53001A,B	Adverse Drug. Exp. Rpt. Regul (Foreign)	1.0	1.0	
53001C	Risk Evaluation Mitigation System (REMS)		2.0	
<b>53</b>	<b>Postmarket Surv. &amp; Epidemiology</b>	<b>11.0</b>	<b>11.0</b>	
56002A-D,F	Drug Process Inspections-Domestic	84.0	69.4	-14.6
56002E	Drug Process Inspections - Gas Manufacturers	5.0	6.0	1.0
56002A-D,F	Foreign Drug Inspections	34.0	40.0	6.0
56002M	Drug Process Inspections - Biotech Manufacturers		4.0	
56008A	Drug Product Surveillance (Domestic)	20.0	17.0	-3.0
56008H	Drug Product Surveillance (Import)	30.9	33.9	3.0
56021A,B	Drug Quality Reporting Systems-DQRS	4.5	4.5	
56022	Enforcement of Rx Drug Marketing Act	2.0	2.0	
56843	Post-Approval Inspections/Investigations (Domestic)	2.0	2.0	
56843	Post-Approval Inspections/Investigations (Foreign)	2.0	2.0	
56D015	Pharmacy Compounding Assignments	5.0	5.0	
56R838	Forensic Evaluation and Sample Analysis	10.0	10.0	
<b>56</b>	<b>Drug Quality Assurance</b>	<b>199.4</b>	<b>195.8</b>	<b>-3.6</b>
63001	Internet, Health Fraud, & OTC Monographs	4.5	4.5	
63002	New Drugs (Prescription) Not Covered by Approved NDAs	5.0	5.0	
<b>63</b>	<b>Unapproved &amp; Misbranded Drugs</b>	<b>9.5</b>	<b>9.5</b>	
88--	Shelf Life Extension Projects	12.0	12.0	
	United States Pharmacopeia (USP) Reference	7.0	7.0	
<b>88</b>	<b>Interagency Cooperative Activities</b>	<b>19.0</b>	<b>19.0</b>	
	<b>Total Mission Direct: Pre and Annual Planned FTEs</b>	<b>339.0</b>	<b>340.0</b>	<b>1.0</b>

# ANIMAL DRUGS AND FEEDS

## FY 2010 WORKPLAN CHANGES

		WORKPLAN FTEs FY 2009	WORKPLAN FTEs FY 2010	FTE DIFFERENCE
<b>PAC</b>	<b>PROGRAM/ASSIGNMENT</b>			
68001	NADA Pre-Approval Inspections	2.9	4.0	1.1
68808	(Pre-Market) GLP and Spon/Mon/Com	2.0	2.0	
68810*	Sponsors Contract Research Orgs./Monitors	*	*	
68811	(Pre-Market) Clinical Investigators	2.4	2.4	
<b>68</b>	<b>Pre-Approval Eval. of Animal Drugs &amp; Food Additives</b>	<b>7.3</b>	<b>8.4</b>	<b>1.1</b>
71001A,B**	Animal Drug Manufacturing Inspections	8.4	12.3	3.9
71003A-J	Feed Contaminants	18.3	19.4	1.1
71004A	Feed Manufacturing	4.2	4.5	0.3
71006	Illegal Drug Residues in Meat and Poultry	16.9	31.9	15.0
71009, 71R844***	Ruminant Feed Ban Rule (BSE) Program	54.4	39.6	-14.8
71R816	Methods Validation/Development Program	5.0	5.0	
71R831, 71R838	Forensic Evaluation and Sample Analysis	1.0	1.0	
71V800	Center Initiated Assignments	2.6	1.0	-1.6
71R852	Pandemic Preparedness (CANCELLED)			
<b>71</b>	<b>Monitoring of Marketed Animal Drugs, Feed, &amp; Devices</b>	<b>110.8</b>	<b>114.7</b>	<b>3.9</b>
	<b>Total Mission Direct: Pre and Annual Planned FTEs</b>	<b>118.1</b>	<b>123.1</b>	<b>5.0</b>

\* 68810 planned under 68808

\*\* 71005 / A planned under 71001

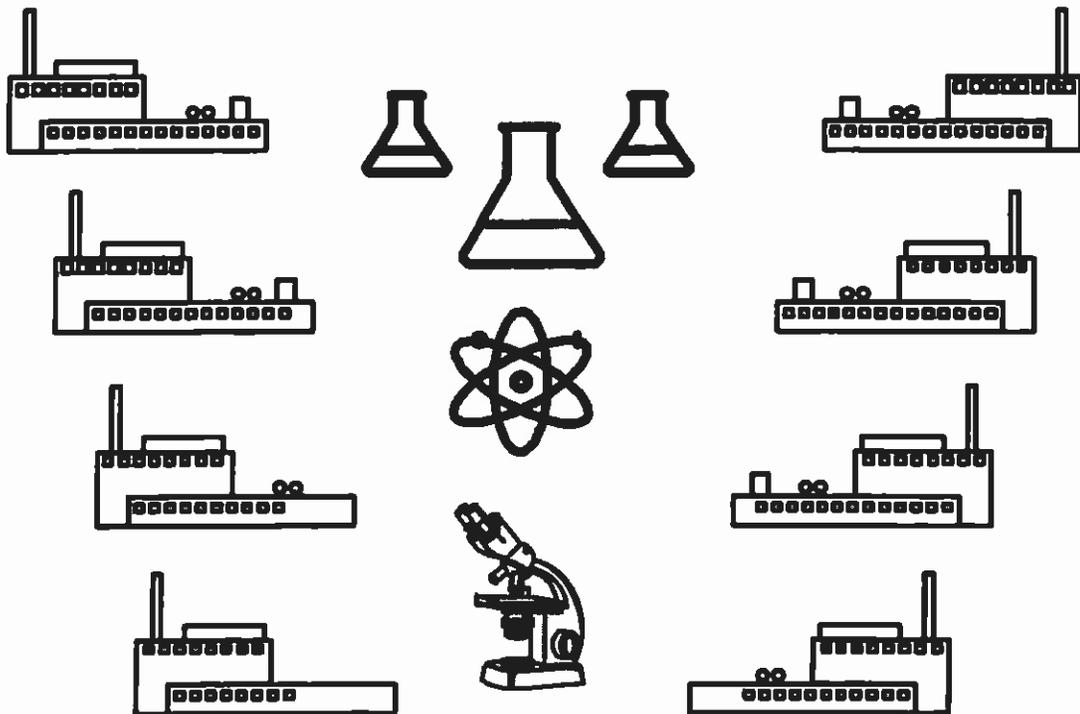
\*\*\* Includes 71R833, 99R833, and 71R824

# MEDICAL DEVICES AND RADIOLOGICAL HEALTH

## FY 2010 WORKPLAN CHANGES

PAC	PROGRAM/ASSIGNMENT	WORKPLAN FTEs FY 2009	WORKPLAN FTEs FY 2010	FTE DIFFERENCE
81010	Med Dev Problem Reporting-MDR/DEN F/U	0.5	0.5	
<b>81</b>	<b>Postmarket Assurance: Devices</b>	<b>0.5</b>	<b>0.5</b>	
82008	Monitoring Device of Foreign Origin-Imports	29.1	38.5	9.4
82845A,B,C,G,S	Inspection of Medical Dev Mfgs: GMP Domestic	92.9	97.6	4.7
82845B	Inspection of Medical Dev Mfgs: GMP Foreign	17.2	19.6	2.4
82845P	Inspection of Accredited Persons: MDUFMA	0.5	0.5	
82845J	Audits of Accredited Persons	0.3	0.3	
822002	Condom Assignment	3.6	3.6	
822003	Mfgs & Importers of Surgical/Exam Gloves	6.5	7.5	1.0
822005	BSE Assignment (CANCELLED)			
822800	Center Initiated Assignments	1.0	1.0	
82R816	Methods Validation/Development Program	2.0	2.0	
82R838	Forensic Evaluation and Sample Analysis	0.3	0.3	
<b>82</b>	<b>Compliance: Devices</b>	<b>153.4</b>	<b>170.9</b>	<b>17.5</b>
83001/A	Med Dev Premkt/Postmkt Insp Domestic	7.1	7.1	
83001/A	Med Dev Premkt/Postmkt Insp Foreign	2.6	2.6	
83808-11	Bioresearch Monitoring Domestic	24.5	24.1	-0.4
83810-11	Bioresearch Monitoring Foreign	0.8	1.2	0.4
<b>83</b>	<b>Project Evaluation: Devices</b>	<b>35.0</b>	<b>35.0</b>	
842002	Test Method Development & Evaluation	3.7	3.7	
84R816	Methods Validation/Development Program	1.0	1.0	
<b>84</b>	<b>Science: Devices</b>	<b>4.7</b>	<b>4.7</b>	
85014	Mammography Facilities Insp Program Domestic	14.5	14.5	
85014	Mammography Facilities Insp Program Foreign	0.1	0.1	
<b>85</b>	<b>Mammography Quality Standards Act (MQSA)</b>	<b>14.6</b>	<b>14.6</b>	
86001	Inspection of Mfgs of Laser Products Domestic	4.2	4.3	0.1
86001	Inspection of Mfgs of Laser Products Foreign	0.2	0.2	
86002	Field Implementation of Sunlamp Products	0.3	0.3	
86003	Field Compliance Testing of Diag X-Ray Equip Domestic	7.8	7.6	-0.2
86003	Field Compliance Testing of Diag X-Ray Equip Foreign	0.7	1.0	0.3
86004	Field Compliance Testing of Cab X-Ray Equip	0.5	0.5	
86006A,B,D,E	Compliance Testing of Elec Prod at WEAC Domestic	3.1	3.1	
86006	Compliance Testing of Elec Prod at WEAC Foreign	0.8	0.8	
86007	Imported Electronic Products	7.2	7.5	0.3
86008	Med Dev & Rad Hlth Use Control & Policy Implementation	3.0	3.0	
86009	Emergency Planning & Response Activities	2.0	2.0	
<b>86</b>	<b>Radiation Control &amp; Health Safety Act (RCHSA)</b>	<b>29.8</b>	<b>30.3</b>	<b>0.5</b>
	<b>Total Mission Direct: Pre and Annual Planned FTEs</b>	<b>238.0</b>	<b>256.0</b>	<b>18.0</b>

# FY 2010 SERVICING LABORATORIES



*THE FOLLOWING PAGES SHOW THE SERVICING  
LABORATORIES FOR EACH COLLECTING DISTRICT  
AND FOR EACH COMPLIANCE PROGRAM OR SUB PART*

**OCTOBER 2009**













**RESOURCE SUMMARY BY PROGRAM CATEGORY  
FY 2010**

	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs
	DOMESTIC	IMPORT	FOREIGN	
<b>TOTAL ALL PROGRAMS</b>	1210.4	611.1	142.0	1963.5
<b>FOODS AND COSMETICS</b>	604.3	501.3	17.8	1123.4
<b>BIOLOGICS</b>	110.8	3.5	6.7	121.0
<b>HUMAN DRUGS</b>	219.6	33.9	86.5	340.0
<b>ANIMAL DRUGS AND FEEDS</b>	101.3	16.3	5.5	123.1
<b>MEDICAL DEVICES AND RADIOLOGICAL HEALTH</b>	174.4	56.1	25.5	256.0

**CENTER FOR FOOD SAFETY AND APPLIED NUTRITION  
RESOURCE SUMMARY  
FY 2010**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs
		DOMESTIC	IMPORT	FOREIGN	
	<b>TOTAL</b>	604.3	501.3	17.8	1123.4
3	FOODBORNE BIOLOGICAL HAZARDS	364.0	385.2	16.6	765.8
4	PESTICIDES AND CHEMICAL AND CONTAMINANTS	104.4	76.5	0.4	181.3
7	MOLECULAR BIOLOGY AND NATURAL TOXINS	13.8	5.3		19.1
9	FOOD AND COLOR ADDITIVES PETITION REVIEW AND POLICY DEVELOPMENT		14.5	0.1	14.6
18	TECHNICAL ASSISTANCE: FOOD AND COSMETICS	82.9			82.9
21	FOOD COMPOSITION, STANDARDS, LABELING AND ECONOMICS	36.2	15.3	0.6	52.1
29	COLOR AND COSMETICS TECHNOLOGY	3.0	4.5	0.1	7.6



1. PROGRAM/ASSIGNMENT TITLE Import Acidified and Low Acid Canned Foods	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) 03003 LACF Products, 03003A Acidified Products	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 19.8
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2. IMPORT FIELD EXAMS	4. IMPORT SAMPLE COLLECTION	4. IMPORT SAMPLE COLL. MICRO GUIDANCE	4. IMPORT SAMPLE COLL. CHEM GUIDANCE	8. IMPORT SAMPLES TO BE ANALYZED MICRO	8. IMPORT SAMPLES TO BE ANALYZED CHEM	IMPORT INVESTI- GATIONS (HOURS)	FOREIGN INSPEC- TIONS	9. OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	5700	1400	1300	100	1300	100	684	170	
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	0.5	1.8			7.0	10.0		27.0	
	TOTAL HOURS	2850	2520			9100	1000	684	4590	
	CONVERSION FACTOR	950	950			1180	1180	950	950	
	TOTAL OPERATIONAL FTES	3.00	2.65			7.71	0.85	0.72	4.83	

9. REMARKS

\* Import Field Exams Hours are for Field Exams as required by the District to cover program priorities. Import Field Exams are to routinely include: verification that the imported product is the same as declared (Reconciliation Exam); and assessment of security concerns related to labeling & source country (including container integrity, signs of intentional adulteration, etc.); traditional safety concerns. These activities are to be reported as a single Import Field Exam under this Compliance Program and PAC. Only one exam should be reported per line entry. Only in the event of a Pre-Determined "for cause" CT Exam, or in the event CT suspicions are raised while conducting routine work requiring follow-up, should the CT Exam be reported under the CT PAC (03R845, 04R845, etc.). See IOM Section 5.4.1.4 for additional information on Food & Cosmetic activities.

\*\*\* Note: SWID Samples collected from TX & NM are to be sent to ARL; and SWID samples collected from CA & AZ are to be sent to PRS.

(b)(2)&(b)(7)(E)

Surveillance activities under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, this program unless otherwise directed.

1. PROGRAM/ASSIGNMENT TITLE Domestic & Imported Cheese & Cheese Products	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) 03037, 03037B, 03037D	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 22.2
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	7	IMPORT SAMPLE COLL MICRO	GUIDANCE IMPORT SAMPLE COLL CHEM / FILTH (4)	IMPORT SAMPLES ANALYZED MICRO	IMPORT SAMPLES ANALYZED CHEM	FOREIGN INSPEC- TIONS
		DOMESTIC INSPEC- TIONS (1)	DOMESTIC INVESTI- GATION HOURS (2)	DOMESTIC SAMPLE COLL (3)	DOMESTIC SAMPLE ANALYSIS MICRO					
	TOTAL FIELD	216	760	270	270	630	75	630	75	40

	HEADQUARTERS	(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	NEW ENGLAND	(b)(2)&(b)(7)(E)								
	NEW YORK	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	WEAC	(b)(2)&(b)(7)(E)								
CE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	BALTIMORE	(b)(2)&(b)(7)(E)								
	CHICAGO	(b)(2)&(b)(7)(E)								
	CINCINNATI	(b)(2)&(b)(7)(E)								
	DETROIT	(b)(2)&(b)(7)(E)								
	MINNEAPOLIS	(b)(2)&(b)(7)(E)								
	NEW JERSEY	(b)(2)&(b)(7)(E)								
	PHILADELPHIA	(b)(2)&(b)(7)(E)								
SE	FORENSIC CHEM. CTR	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	ATLANTA	(b)(2)&(b)(7)(E)								
	FLORIDA	(b)(2)&(b)(7)(E)								
	NEW ORLEANS	(b)(2)&(b)(7)(E)								
SW	SAN JUAN	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	DALLAS	(b)(2)&(b)(7)(E)								
	DENVER	(b)(2)&(b)(7)(E)								
PA	KANSAS CITY	(b)(2)&(b)(7)(E)								
	SOUTHWEST IMPORT DISTRICT	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	LOS ANGELES	(b)(2)&(b)(7)(E)								
	SAN FRANCISCO	(b)(2)&(b)(7)(E)								
	SEATTLE	(b)(2)&(b)(7)(E)								
	PACIFIC REGIONAL LAB - SW	(b)(2)&(b)(7)(E)								
	PACIFIC REGIONAL LAB - NW	(b)(2)&(b)(7)(E)								
	HOURS PER OPERATION	18.0		4.0	18.0	2.0		18.0	6.1	18.0
	TOTAL HOURS	3888	760	1080	4860	1260		11340	458	720
	CONVERSION FACTOR	950	950	950	1180	950		1180	1180	950
	TOTAL OPERATIONAL FTES	4.09	0.80	1.14	4.12	1.33		9.81	0.39	0.76

9. REMARKS

- Domestic Firm Inspection Priority: soft cheese (i.e. soft-fresh, semi-soft and soft-ripened) manufacturers first, hard cheese manufacturers second, and cheese product manufacturers last. Prioritize inspections to look at small manufacturers i.e. artisanal and farmstead cheese manufacturers producing high risk cheese which distribute cheese in interstate commerce. High risk firms whose last inspection was NAI may be placed on a 3 year inspection frequency.
- Investigation Hours are provided for assignments to cover the investigation of raw milk cheese (based on inspection time).
- Domestic Sample Collection - districts may collect both compliance and surveillance samples according to the guidance in the compliance program to fulfill their sampling obligation. If no problems are observed at the firm, the districts may accomplish sampling obligations by collecting samples during the inspection, or by collecting samples at the wholesale / retail level.
- Filth analysis should be done as needed on split import samples collected for more than one attribute.

Note: send SWID samples collected from TX & NM to NRL; send SWID samples collected from CA & AZ to NRL.

1. PROGRAM/ASSIGNMENT TITLE Domestic Acidified & Low Acid Canned Food	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) 03803A *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 13.9
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS  (1)	2 INVESTI- GATION HOURS	2 FIELD EXAMS HOURS  (2)	9 DOMESTIC SAMPLE COLLECTIONS  (3)	4 DOMESTIC SAMPLE COLL. MICRO GUIDANCE	5 DOMESTIC SAMPLE COLL. CHEM GUIDANCE	8 DOMESTIC SAMPLES TO BE ANALYZED MICRO	8 DOMESTIC SAMPLES TO BE ANALYZED CHEM	9 BETTER PROCESSING SCHOOL TRAINING (HOURS) (4)
	<b>TOTAL FIELD</b>	<b>260</b>		<b>1520</b>	<b>180</b>	<b>160</b>	<b>20</b>	<b>160</b>	<b>20</b>	<b>760</b>

	HEADQUARTERS	(b)(2)&(b)(7)(E)																	
NE	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
	WEAC																		
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
	FORENSIC CHEM. CTR																		
SE	REGIONAL STAFF																		
	ATLANTA																		
	FLORIDA																		
	NEW ORLEANS																		
	SAN JUAN																		
	REGIONAL LAB																		
SW	REGIONAL STAFF																		
	DALLAS																		
	DENVER																		
	KANSAS CITY																		
	SOUTHWEST IMPORT DISTRICT																		
	REGIONAL LAB																		
PA	REGIONAL STAFF																		
	LOS ANGELES																		
	SAN FRANCISCO																		
	SEATTLE																		
	PACIFIC REGIONAL LAB - SW																		
	PACIFIC REGIONAL LAB - NW																		
	<b>HOURS PER OPERATION</b>										<b>30.0</b>			<b>6.0</b>			<b>14.0</b>	<b>14.0</b>	
	<b>TOTAL HOURS</b>										<b>7800</b>		<b>1520</b>	<b>1080</b>			<b>2240</b>	<b>280</b>	<b>760</b>
	<b>CONVERSION FACTOR</b>										<b>950</b>		<b>950</b>	<b>950</b>			<b>1180</b>	<b>1180</b>	<b>950</b>
	<b>TOTAL OPERATIONAL FTES</b>										<b>8.21</b>		<b>1.60</b>	<b>1.14</b>			<b>1.90</b>	<b>0.24</b>	<b>0.80</b>

9. REMARKS

\* Report all resources expended for NLEA under PAC 21005.  
 PAC 03R839 Response to Foodborne Emergencies - use when needed.  
 PAC 03803 is for inspections of central distribution warehouses where unlabeled cans are shipped for labeling and casing, and follow up inspections of LACF/AF products for filth only.

- 1) Inspect NAI firms on a 3 year inspection cycle. State inspections may be conducted in addition to the number of inspections assigned per district.
- 2) Field Exams are to include pH and canned seam evaluation.
- 3) Planned DSC are for projected "for cause" sampling.
- 4) Resources are for attendance at Better Processing Schools (BPS).

Surveillance activities under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under and credited to the program PAC unless otherwise directed.

1. PROGRAM/ASSIGNMENT TITLE Domestic Food Safety	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) 03803,B,C,D,E *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 107.2
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R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	1	2	DOMESTIC	GUIDANCE	DSA	DOMESTIC	DOMESTIC																																																																	
		INSP CTIONS INCL HIGH RISK (1)	INVEST GATIONS (HOURS) INCL NAT'L EXPERT	SAMPLE COLL (2)	DOMESTIC SAMPLE COLL SURVEILLANCE	MICRO SALMONELLA SEROTYPING (HOURS) (3)	SAMPLES TO BE ANALYZED MICRO	SAMPLES TO BE ANALYZED CHEM																																																																	
	TOTAL FIELD	4100	20500	410	100	1344	246	164																																																																	
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)																																																																							
	REGIONAL STAFF																																																																								
	NEW ENGLAND																																																																								
	NEW YORK																																																																								
	REGIONAL LAB																																																																								
	WEAC																																																																								
CE	REGIONAL STAFF										(b)(2)&(b)(7)(E)																																																														
	BALTIMORE																																																																								
	CHICAGO																																																																								
	CINCINNATI																																																																								
	DETROIT																																																																								
	MINNEAPOLIS																																																																								
	NEW JERSEY																																																																								
	PHILADELPHIA																																																																								
	FORENSIC CHEM. CTR																																																																								
	REGIONAL STAFF																																																																								
SE	ATLANTA																			(b)(2)&(b)(7)(E)																																																					
	FLORIDA																																																																								
	NEW ORLEANS																																																																								
	SAN JUAN																																																																								
	REGIONAL LAB																																																																								
SW	REGIONAL STAFF																												(b)(2)&(b)(7)(E)																																												
	DALLAS																																																																								
	DENVER																																																																								
	KANSAS CITY																																																																								
	SOUTHWEST IMPORT DISTRICT																																																																								
PA	REGIONAL LAB																																					(b)(2)&(b)(7)(E)																																			
	REGIONAL STAFF																																																																								
	LOS ANGELES																																																																								
	SAN FRANCISCO																																																																								
	SEATTLE																																																																								
	PACIFIC REGIONAL LAB - SW																																														(b)(2)&(b)(7)(E)																										
	PACIFIC REGIONAL LAB - NW																																																							(b)(2)&(b)(7)(E)																	
	HOURS PER OPERATION																																																																18.0		6.0			12.0	12.0		
	TOTAL HOURS																																																																73800	20500	2460		1344	2952	1968		
	CONVERSION FACTOR																																																																950	950	950		1180	1180	1180		
	TOTAL OPERATIONAL FTES																																																																77.68	21.58	2.59		1.14	2.50	1.67		

9. REMARKS

\* Resources for PACs 04803 and 09803E,F are included. Resources for audits are under State Contracts Program PAC 03R843. Assignments for sprout producers and egg farms, if needed, will be taken from this program. Non Seafood Inspections for EU and Chilean Certification will be handled by CFSAN Assignment and counted against inspectional obligations of this program. For Non-Clinical Good Laboratory Practice Inspections CFSAN will contact affected Districts to arrange inspections during the course of the year.

(1) Allergen Inspections may be assigned upon the issuance of an Allergen Program For Assignment for FY10.  
**Do Not Initiate Surveillance Allergen Inspections until a New Allergen Program is issued.**  
**Report Allergen inspections under PAC 03803E. "For Cause" Allergen Inspections are to be conducted as needed.**

(2) A portion of Domestic Sample Collection resources are set aside for targeted Risk Based Surveillance Assignments in FY10.

(3) Salmonella Serotyping: Samples generated from SRL & ARL go to ARL; Samples generated from other labs go to Denver.

1 PROGRAM/ASSIGNMENT TITLE Imported Foods General	2 PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3 PROGRAM/ASSIGNMENT CODE(S) 03819, A,B,C (03R833,03R824,99R833) *	4 WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5 OPERATIONAL FTE POSITIONS 246.4
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R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	IMPORT ENTRY REVIEW (Hours) (1)	PRIOR NOTICE REVIEW (Hours) (2)	IMPORT INVESTIGATIONS (Hours) (3)	IMPORT FIELD EXAMS	IMPORT SAMPLE COLL	GUIDANCE IMPORT SAMPLE COLL MICRO	GUIDANCE IMPORT SAMPLE COLL CHEM	IMPORT SAMPLE ANALYSIS MICRO	IMPORT SAMPLES ANALYSIS CHEM	IMPORT SAMPLES ANALYSIS SALMONELLA RESISTANT (Hours)	OP CODE 92 PRIVATE LAB REVIEW (Hours)	FOREIGN INSPEC- TIONS
	<b>TOTAL FIELD</b>	98004	30000	10165	100800	7500	4850	2650	4850	2650	1180	3540	130

(b)(2)&(b)(7)(E)

NE	HEADQUARTERS												
	REGIONAL STAFF												
	NEW ENGLAND												
	NEW YORK												
	REGIONAL LAB												
WEAC													
CE	REGIONAL STAFF												
	BALTIMORE												
	CHICAGO												
	CINCINNATI												
	DETROIT												
	MINNEAPOLIS												
	NEW JERSEY												
	PHILADELPHIA												
	FORENSIC CHEM. CTR												
SE	REGIONAL STAFF												
	ATLANTA												
	FLORIDA												
	NEW ORLEANS												
	SAN JUAN												
SW	REGIONAL LAB												
	REGIONAL STAFF												
	DALLAS												
	DENVER												
	KANSAS CITY												
PA	SOUTHWEST IMPORT DISTRICT												
	REGIONAL LAB												
	REGIONAL STAFF												
	LOS ANGELES												
	SAN FRANCISCO												
SEATTLE													
PACIFIC REGIONAL LAB - SW													
PACIFIC REGIONAL LAB - NW													

HOURS PER OPERATION				0.5	2.2				8.2	7.9			30.0
TOTAL HOURS	98004	30000	10165	50400	16500				39770	19875	1180	3540	3900
CONVERSION FACTOR	1200	1200	950	950	950				1180	1180	1180	1180	950
TOTAL OPERATIONAL FTES	81.67	25.00	10.70	53.05	17.37				33.70	16.84	1.00	3.00	4.11

**8. REMARKS**

\* Resources in this program can be used to report Import Food Activities under the following PACs: 03R833 - Import/Entry Review Hours; 99R833 - Evaluation Hours; 03R824 - Follow-Up to Refusal.

**\*\* Private Laboratory Review Time is for NRL, SRL, PRS analysts to review private lab results submitted for imported foods. Review time MUST be reported under Miscellaneous Operation Code 92 with "PL" in the FACTS description field. Without consistency in reporting, your time will not be found and credited.**

(1) **Import Entry Review Hours:** resources for these activities cover All Import Food Programs.

(2) Resources in Headquarters are for review of prior notices at the Prior Notice Center.

(3) **Investigation Hours:** resources are for Import Field Exams, Import Filer Evaluations, Follow-up to Refusals (marking and tracking the disposition of detained lots) and other operations as required by the District to cover program priorities. Districts should report time under the appropriate operation and PAC for the activities performed.

Note: Additional time for Import Field Exams under investigation hours is planned in the Import LACF, Import Seafood and Toxic Elements Program.

All Import Field Exams are to Routinely Include the Following:

(a) Verification that the Imported Product is the same as that which was declared (Reconciliation Exam);

(b) An Assessment of Security Concerns Related to Labeling & Source Country (Including Container Integrity, Signs of Intentional Adulteration, etc.);

(c) Traditional Safety Concerns.

These Activities are to be Reported as a Single Import Field Exam under this Compliance Program and PAC. Only One Exam should be Reported Per Line Entry. Only in the Event of a Pre-Determined "For Cause" CT Exam, Or in the Event CT Suspicions Are Raised Conducting Routine Follow-Up, Should an Additional Exam and Time be Reported Under the CT PAC (03R845, 04R845, etc.)

See IOM Section 530.04 for Additional Information on Food and Cosmetic Defense Activities.

Import Samples to be Analyzed - Salmonella Resistant (Hours) will be performed by Denver Laboratory.

Note: Please Review CFSAN's Import Risk Priorities List Available on Inside.FDA.Gov.

1. PROGRAM/ASSIGNMENT TITLE Domestic Fish & Fishery Products	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) 03842,B, C, D, H *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 44.1
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS (1)	3 DOMESTIC SAMPLE COLL (2)	3 GUIDANCE DOMESTIC SAMPLE COLL MICRO 210	3 GUIDANCE DOMESTIC SAMPLE COLL CHEM 70	DOMESTIC SAMPLE ANALYSIS MICRO 210	DOMESTIC SAMPLE ANALYSIS CHEM 70	Nat'l Expert Hrs DOMESTIC SAMPLE ANALYSIS ORGANO EXAM (3) 320	LEVEL II AUDITORS CERTI- FICATION HOURS (4) 1600
	<b>TOTAL FIELD</b>	1370	260	210	70	210	70	320	1600

	HEADQUARTERS	(b)(2)&(b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
SE	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
SW	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
PA	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LAB - SW								
	PACIFIC REGIONAL LAB - NW								

HOURS PER OPERATION	25.6	5.0			17.0	13.0			
TOTAL HOURS	35072	1400			3570	910	320		1600
CONVERSION FACTOR	950	950			1180	1180	1180		950
TOTAL OPERATIONAL FTES	36.92	1.47			3.03	0.77	0.27		1.68

9. REMARKS

\* Additional PACs: 03R839; 04842A,H; 07842,H; 09842E,F,H; 21842, 21R829

(1) High Risk Potential Products (HRPP) processors whose last two inspections were NAI can be considered for a 2-year inspection cycle unless the firm has added a new high risk seafood product to their line.

(2) Domestic Sample Collections: seafood collections are planned "For Cause Only." The number of samples planned per district are not to be considered a goal or target. Only collect "For Cause" samples following the guidance in Part III, page 5, Section E.1 of the compliance program. Verification samples are not to be collected.

(3) Organoleptic National Expert time

(4) Level II Auditors Certification Time: These hours are to provide auditors the time to evaluate/train other investigators trying to maintain Level II Certification.

Note: EU Certification has been deleted because in June 2009 this responsibility was transferred to NOAA.

<b>1 PROGRAM/ASSIGNMENT TITLE</b> Import Seafood Products	<b>2. PPS PROJECT NAME/NUMBER</b> Foodborne Biological Hazards - 03
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<b>3 PROGRAM/ASSIGNMENT CODE(S)</b> 03844,B,C,D,H §	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> 91.7
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	6	1	2	4	4	4	8	8	8	10	10
REG I O N	DISTRICT/ SPECIALIZED LABORATORY	IMPORTER INSP 03844H	IMPORT INVESTI- GATION HOURS **	IMPORT SAMPLE COLL PHYSICAL ***	GUIDANCE IMPORT SAMPLE COLL MICRO	GUIDANCE IMPORT SAMPLE COLL CHEM	IMPORT SAMPLE ANALYSIS MICRO ****	IMPORT SAMPLE ANALYSIS CHEM ****	Nat'l Experts ISAs ORGANO ANALYSIS HOURS	IMPORT FIELD EXAMS	FOREIGN INSPEC- TIONS
	<b>TOTAL FIELD</b>	375	1700	6400	4480	3050	4480	3050	1180	11200	170

	HEADQUARTERS	(b)(2)&(b)(7)(E)									
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
SW	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
PA	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LAB - SW										
	PACIFIC REGIONAL LAB - NW										

HOURS PER OPERATION	14.0		2.8			11.0	5.3		0.5	25.0
<b>TOTAL HOURS</b>	5250	1700	16640			49280	16185	1180	5600	4250
<b>CONVERSION FACTOR</b>	950	950	950			1180	1180	1180	950	950
<b>TOTAL OPERATIONAL FTES</b>	5.53	1.79	17.52			41.76	13.70	1.00	5.89	4.47

**8 REMARKS**

\* Inspections of Importers are to ascertain if the importer has complied with Seafood HACCP Regulations, not to perform filer inspections

\*\* Import Investigations Hours are for Field Exams, Label exams, & other operations as required by the District to cover program priorities. Report time under the appropriate operations & PAC for activities performed.

\*\*\* Import Sample Collection reflects CFSAN's top 3 priority products: Ready to Eat (RTE), Modified Atmosphere Packaging (MAP), & Histamine Forming. Districts with high volume of CFSAN's top 3 priorities will note an increase in sample collections. All Districts should concentrate on collections as per the priorities set in the Import Seafood Compliance Program (C.P.). When physical samples are collected for analysis, the guidance in the C.P. should be followed in determining what the product should be analyzed for. Specifically: raw scombrotoxic fish should be analyzed for histamine, not for MICRO; raw shrimp should be analyzed for undeclared sulfite (&/or chemotherapeutics under PAC 04018 following the guidance in the C.P.), not for MICRO. All Import Field Exams are to routinely include the following: a) Verification that the imported product is the same as that All Import Field Exams are to routinely include the following: a) Verification that the imported product is the same as that which was declared (Reconciliation Exam); b) An assessment of security concerns related to labeling & source country, including container integrity, signs of intentional adulteration, etc.; c) Traditional safety concerns.

These activities are to be reported as a single Import Field Exam under this C.P. & PAC. Only one exam should be reported per line entry. Only in the event of a pre-determined "For Cause" CT Exam, or in the event CT suspicions are raised conducting routine follow-up, should an additional exam & time be reported under the CT PAC (03R845,04R845,etc.). See IOM Section 5.4.1.4 for additional information on Food & Cosmetic Defense Activities.

\*\*\*\* Multiple Analyses will be run on numerous samples, both Micro & Chem, therefore analyses outnumber collections.

Note: NWE-DO will collect 76 MICRO & 119 CHEM samples to be sent to WEAC Lab for analyses. SWID samples collected for TX & NM are to be sent to ARL; SWID samples collected for CA & AZ are to be sent to PRS.

§ Other PACs include: 07844; 09844E,F; 21844

1. PROGRAM/ASSIGNMENT TITLE Juice HACCP Inspection Program	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) 03847H, 03847 *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 7.7
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	3	3	3	7	7	1								
		DOMESTIC INSP CTIONS	IMPOR T INSP CTIONS	DOMESTIC SAMP LE COLL	GUIDANCE IMPOR T SAMP LE COLL MICRO	GUIDANCE IMPOR T SAMP LE COLL CHEM	DOMESTIC SAMP LE ANALYSIS MICRO	DOMESTIC SAMP LE ANALYSIS CHEM	FOREIGN INSP CTIONS								
	<b>TOTAL FIELD</b>	<b>200</b>	<b>100</b>	<b>75</b>	<b>55</b>	<b>20</b>	<b>55</b>	<b>20</b>	<b>40</b>								
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)															
	REGIONAL STAFF																
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
WEAC																	
CE	REGIONAL STAFF																
	BALTIMORE																
	CHICAGO																
	CINCINNATI																
	DETROIT																
	MINNEAPOLIS																
	NEW JERSEY																
	PHILADELPHIA																
	FORENSIC CHEM. CTR																
SE	REGIONAL STAFF																
	ATLANTA																
	FLORIDA																
	NEW ORLEANS																
	SAN JUAN																
SW	REGIONAL LAB																
	REGIONAL STAFF																
	DALLAS																
	DENVER																
	KANSAS CITY																
PA	SOUTHWEST IMPORT DISTRICT																
	REGIONAL LAB																
	REGIONAL STAFF																
	LOS ANGELES																
	SAN FRANCISCO																
	SEATTLE																
	PACIFIC REGIONAL LAB - SW																
	PACIFIC REGIONAL LAB - NW																
<b>HOURS PER OPERATION</b>										20.0	13.0	5.0			15.0	11.0	20.0
<b>TOTAL HOURS</b>										4000	1300	375			825	220	800
<b>CONVERSION FACTOR</b>										950	950	950			1180	1180	950
<b>TOTAL OPERATIONAL FTES</b>										4.21	1.37	0.39			0.70	0.19	0.84

9. REMARKS

\* Additional related PACs: 04847; 04847,H; 07847, 07847,H; 09847,H; 21847H. Use PAC 03847 for General Sanitation Issues (non-HACCP).  
 Use "H" PACs for HACCP Verifications Samples and the HACCP component of inspection.  
 Use Non "H" PACs for "For Cause" samples and filth/sanitation component of inspection.

State inspections may be conducted in addition to the number of inspections assigned per district (PAC 03S004). Resources have been added to cover food security issues at all domestic processor inspections. Inspectional priority is as follows: firms associated with recent outbreaks, unpasteurized juice firms, firms whose previous inspections were OAI, and firms that have not yet been inspected.

DSC resources have been provided for anticipated "for cause" and verification" samples.

Note: Surveillance activities planned under this program may be pre-empted by enforcement initiatives agreed upon by ORA and CFSAN. Such initiatives will be reported under, and credited to, the Program PAC unless otherwise directed.

1. PROGRAM/ASSIGNMENT TITLE Imported & Domestic Micro Assignments	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
--	---

3. PROGRAM/ASSIGNMENT CODE(S) 03F098 Import 03F100 Domestic	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 48.9
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2. INVESTI- GATIONS (Hours)	3. DOMESTIC SAMPLE COLL	4. IMPORT SAMPLE COLL	7. DOMESTIC SAMPLE ANALYSIS MICRO	8. IMPORT SAMPLE ANALYSIS MICRO	7. HIGH THROUGHPUT LABRATORIES DOMESTIC SAMPLE ANALYSIS	8. HIGH THROUGHPUT LABRATORIES IMPORT SAMPLE ANALYSIS	8. IMPORT SAMPLES TO BE ANALYZED	9. OTHER OPERATIONS (Hours)							
	<b>TOTAL FIELD</b>	1100	700	1000	645	647	442	443									
	HEADQUARTERS	(b)(2)&(b)(7)(E)															
NE	REGIONAL STAFF																
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
	WEAC																
CE	REGIONAL STAFF																
	BALTIMORE																
	CHICAGO																
	CINCINNATI																
	DETROIT																
	MINNEAPOLIS																
	NEW JERSEY																
	PHILADELPHIA																
	FORENSIC CHEM. CTR																
SE	REGIONAL STAFF																
	ATLANTA																
	FLORIDA																
	NEW ORLEANS																
	SAN JUAN																
	REGIONAL LAB																
SW	REGIONAL STAFF																
	DALLAS																
	DENVER																
	KANSAS CITY																
	SOUTHWEST IMPORT DISTRICT																
	REGIONAL LAB																
PA	REGIONAL STAFF																
	LOS ANGELES																
	SAN FRANCISCO																
	SEATTLE																
	PACIFIC REGIONAL LAB - SW																
	PACIFIC REGIONAL LAB - NW																
	<b>HOURS PER OPERATION</b>		3.0	3.0	25.0	25.0	20.0	20.0									
	<b>TOTAL HOURS</b>	1100	2100	3000	16125	16175	8840	8860									
	<b>CONVERSION FACTOR</b>	950	950	950	1180	1180	1180	1180									
	<b>TOTAL OPERATIONAL FTES</b>	1.16	2.21	3.16	13.67	13.71	7.49	7.51									

9. REMARKS

\* In FY2010 an additional 300 domestic samples will be collected under state contracts.

CFSAN will work with ORA to determine how resources will be allocated in FY2010.

Note: SWID samples collected from TX & NM are to be sent to ARL.  
 SWID samples collected from CA & AZ are to be sent to DEN.

1. PROGRAM/ASSIGNMENT TITLE CFSAN Environmental Sampling Assignments	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) 03F830, 03R858, 04R858	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 61.1
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R E G I O	DISTRICT/ SPECIALIZED LABORATORY	Environmental SAMPLE COLL Industry 23 C-F FIRMS (1)	Environmental SAMPLE COLL DRY DAIRY FIRMS (2)	Environmental SAMPLE COLL CRAB MEAT FIRMS (3)	Environmental SAMPLE COLL SOFT CHEESE FIRMS (3)	Environmental SAMPLE COLL INFANT FORMULA DRY POWDER (4)	UNPLANNED ASSIGN- MENTS PAC 03R858 PAC 04R858 (5)	Environmental SAMPLE ANALYSES (HOURS)
		TOTAL FIELD	554	14	66	109	23	50

	HEADQUARTERS	(b)(2)&(b)(7)(E)						
NE	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
	WEAC							
CE	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
SE	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	REGIONAL LAB							
SW	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
	REGIONAL LAB							
PA	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LAB - SW							
	PACIFIC REGIONAL LAB - NW							
	HOURS PER OPERATION	40.0	40.0	40.0	40.0	40.0	40.0	
	TOTAL HOURS	22160	560	2640	4360	920	2000	31540
	CONVERSION FACTOR	950	950	950	950	950	950	1180
	TOTAL OPERATIONAL FTES	23.33	0.59	2.78	4.59	0.97	2.11	26.73

9. REMARKS

(1) ORA/DFI will issue inspectional schedule to direct environmental sampling (*Salmonella*).

(2) CFSAN will issue this assignment in the first quarter FY10 (*Listeria*).

(3) CFSAN will issue lists (*Listeria*) to the districts. Firms were selected based on products covered during a previous inspections.

(4) Environmental Sampling (*E. sakazakii* and *Salmonella*) should be conducted during the routine inspection of dry powder infant formula manufacturers.

(5) Resources can be used for Reportable Food Registry Follow-Up Action. Refer to DFI Field Bulletin #34 Foods. PAC 03R858, Reportable Food Registry Activities-MICRO; PAC 04R858 Reportable Food Registry Activities-CHEM

Environmental sampling to follow-up on Outbreaks and Emergency Response activities is planned separately (Response to Foodborne Emergencies, NEC: PACs 03R839 and 04R839). District spread of resources is for planning purposes only. Report inspections and analyses conducted in response to an outbreak and emergency against the appropriate Foodborne Emergency PAC (e.g. 03R855 *Salmonella* in Peanut Butter Emergency/Recall - Human Food Use, 03R266 *Listeria* Emergency, or another PAC to be created in response to a future emergency. Assignments and district inventories will determine resource usage. Analytical resources are spread based on microbiological servicing laboratories.

1. PROGRAM/ASSIGNMENT TITLE Unspecified Foreign Inspections/Assessments	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) 03R233 See Remarks	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.6
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN INSP EC T I O N S	2 INVEST I G A T I O N S  (HOURS)	3 FOREIGN ASSESSMENT TECHNICAL ASSISTANCE (HOURS)	4 DOMESTIC SAMPLE ANALYSIS	5 IMPORT SAMPLE ANALYSIS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>18</b>		<b>950</b>						
NE	HEADQUARTERS	(b)(2)&(b)		(b)(2)&(b)						
	REGIONAL STAFF	(7)(E)		(7)(E)						
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
<b>HOURS PER OPERATION</b>		30.0								
<b>TOTAL HOURS</b>		540		950						
<b>CONVERSION FACTOR</b>		950		950						
<b>TOTAL OPERATIONAL FTES</b>		0.57		1.00						

9. REMARKS

Foreign activities per DFI inspection distribution.

\* Technical Assistance can include, but is not limited to: training, presentations, speeches, site visits, outreach, workshops, seminars or meetings with partnership groups, trade associations, etc.

These resources are set aside for foreign food inspections as yet to be determined.  
**NO INSPECTIONS ARE TO BE REPORTED UNDER PAC 03R233.**  
 Report accomplishments under the program PAC covered during the inspection. CFSAN will determine the type of inspection and provide relevant information to DFI well in advance of dates required for planning trips.

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) 03R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 10.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	METHODS VAL/DEV MICRO (Hours)	APPLIED TECHNOLOGY CENTER MICRO (Hours)							
	<b>TOTAL FIELD</b>	<b>7220</b>	<b>4720</b>							
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	<b>HOURS PER OPERATION</b>									
	<b>TOTAL HOURS</b>	<b>7220</b>	<b>4720</b>							
	<b>CONVERSION FACTOR</b>	<b>1205</b>	<b>1180</b>							
	<b>TOTAL OPERATIONAL FTEs</b>	<b>5.99</b>	<b>4.00</b>							

9. REMARKS

Workload Source: Determined by Division of Field Science, ORO.

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Outbreak and Emergency Response (PPS 03)	<b>2. PPS PROJECT NAME/NUMBER</b> Foodborne Biological Hazards - 03
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<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 03R839	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> 51.2
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	Consumer Safety Officers MICRO (HOURS)	Analysts MICRO (HOURS)	4 IMPORT SAMPLE COLL	7 DOMESTIC SAMPLE ANALYSIS MICRO	8 IMPORT SAMPLE ANALYSIS MICRO	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)	
	<b>TOTAL FIELD</b>	40185	10500								
	HEADQUARTERS	(b)(2)&(b)(7)(E)									
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
FORENSIC CHEM. CTR											
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
SW	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
PA	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LAB - SW										
	PACIFIC REGIONAL LAB - NW										
	<b>HOURS PER OPERATION</b>										
	<b>TOTAL HOURS</b>	40185	10500								
	<b>CONVERSION FACTOR</b>	950	1180								
	<b>TOTAL OPERATIONAL FTES</b>	42.30	8.90								

**9. REMARKS**

Time to be used for all outbreak and emergency activities related to foodborne biological hazards. District spread is for planning purposes only. Report inspections and analyses conducted in response to an outbreak and emergency against the appropriate Foodborne Emergency PAC (e.g. 03R855 *Salmonella* in Peanut Butter Emergency/Recall - Human Food Use, 03R266 *Listeria* Emergency, or another PAC to be created in response to a future emergency).

1. PROGRAM/ASSIGNMENT TITLE Contract Management	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) 03R843	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 12.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 CONTRACT MANAGE- MENT HOURS (1)	2 INVESTI- GATIONS (Hours)	9 FOREIGN ASSESSMENT TECHNICAL ASSISTANCE (HOURS)	4 DOMESTIC SAMPLE ANALYSIS	5 IMPORT SAMPLE ANALYSIS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>11400</b>								
NE	HEADQUARTERS	(b)(2)&(b)								
	REGIONAL STAFF	(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	<b>HOURS PER OPERATION</b>									
	<b>TOTAL HOURS</b>	<b>11400</b>								
	<b>CONVERSION FACTOR</b>	<b>950</b>								
	<b>TOTAL OPERATIONAL FTES</b>	<b>12.00</b>								

9. REMARKS

(1) Time planned for Contract Management includes resources to conduct audits.  
 Note: Non-operational FTEs, i.e. supervisors, should not report contract management time.

Time planned is for time reported under operation code 92, Coordination/Technical Assistance.

1. PROGRAM/ASSIGNMENT TITLE Food Defense	2. PPS PROJECT NAME/NUMBER Foodborne Biological Hazards - 03
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3. PROGRAM/ASSIGNMENT CODE(S) 03R845	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 28.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 CSO DOMESTIC INVESTIGATION HOURS	2 CSO IMPORT INVESTIGATION HOURS	8 IMPORT CHEM ANALYTICAL HOURS	8 IMPORT MICRO ANALYTICAL HOURS	7 DOMESTIC CHEM ANALYTICAL HOURS	7 DOMESTIC MICRO ANALYTICAL HOURS	CHEM HRS FD METHOD VALIDATION INFO ONLY	MICRO HRS FD METHOD VALIDATION INFO ONLY	BIOTERRORISM (BT) FIRM (OEI) MAINTENANCE **
	<b>TOTAL FIELD</b>	<b>8550</b>	<b>1900</b>	<b>2360</b>	<b>1183</b>	<b>5310</b>	<b>4130</b>	<b>900</b>	<b>800</b>	<b>1425</b>

(b)(2)&(b)(7)(E)										
NE	HEADQUARTERS									
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
		REGIONAL STAFF								
SE	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									

HOURS PER OPERATION										4.0
TOTAL HOURS	8550	1900	2360	1183	5310	4130				5700
CONVERSION FACTOR	950	950	1180	1180	1180	1180				950
TOTAL OPERATIONAL FTES	9.00	2.00	2.00	1.00	4.50	3.50				6.00

9. REMARKS  
 Report Food Defense activities under PAC 03R845. Report Expanded Time under PACs: 04R845, 07R845, 09R845, 21R845.

Planned Resources are for all Special Food Defense Related Activities over & above resources for Food Defense Activities that are incorporated into routine safety monitoring activities, i.e. Food Defense coverage during routine Food Safety Inspection & Import & Domestic Food Defense Reconciliation Exams. Resources for Food Defense coverage during routine operations are included in the Parent Programs. Domestic & Import resources have been separated for planning purposes. Based on circumstances, resources may be shifted between Import & Domestic. Resources are to be used for CFSAN Food Defense Assignments for Inspections, Sample Collections, & Analyses, including those to support FERN. Total Lab Time may be used for maintaining General Food Lab Defense Capabilities.

\* Resources for Food Defense Method Validation are a subset of the total Chemist & Microbiologist Resources (planned by Division of Field Science, DFS). These columns are for information only.

\*\* Resources provided are for district determination of new firm workload obligation which is based on Bioterrorism (BT) Legislation.

Note: SWID samples collected from TX & NM are to be sent to ARL. SWID samples collected from CA & AZ are to be sent to PRS.



1. PROGRAM/ASSIGNMENT TITLE Pesticides and Industrial Chemicals in Domestic and Imported Foods	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants -04
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3. PROGRAM/ASSIGNMENT CODE(S) 04004A,D, 04R833, 99R833, 04R824	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 59.5 (32.1)
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	INV (HOURS)	DSCs	DSAs CHEM	DSCs Surveillance	DSCs DIOXINS	DSAs DIOXINS	DSAs DIOXINS	DSCs SEAFOOD	DSAs SEAFOOD
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	NEW ENGLAND	(b)(2)&(b)(7)(E)								
	NEW YORK	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	WEAC	(b)(2)&(b)(7)(E)								
CE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	BALTIMORE	(b)(2)&(b)(7)(E)								
	CHICAGO	(b)(2)&(b)(7)(E)								
	CINCINNATI	(b)(2)&(b)(7)(E)								
	DETROIT	(b)(2)&(b)(7)(E)								
	MINNEAPOLIS	(b)(2)&(b)(7)(E)								
	NEW JERSEY	(b)(2)&(b)(7)(E)								
	PHILADELPHIA	(b)(2)&(b)(7)(E)								
SE	FORENSIC CHEM. CTR	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	ATLANTA	(b)(2)&(b)(7)(E)								
	FLORIDA	(b)(2)&(b)(7)(E)								
	NEW ORLEANS	(b)(2)&(b)(7)(E)								
SW	SAN JUAN	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	DALLAS	(b)(2)&(b)(7)(E)								
	DENVER	(b)(2)&(b)(7)(E)								
PA	KANSAS CITY	(b)(2)&(b)(7)(E)								
	SOUTHWEST IMPORT DISTRICT	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	LOS ANGELES	(b)(2)&(b)(7)(E)								
	SAN FRANCISCO	(b)(2)&(b)(7)(E)								
	SEATTLE	(b)(2)&(b)(7)(E)								
	PACIFIC REGIONAL LABORATORY- SW	(b)(2)&(b)(7)(E)								
	PACIFIC REGIONAL LABORATORY- NW	(b)(2)&(b)(7)(E)								
	HOURS PER OPERATION		3.0	6.5	3.0	4.0	20.0	11.6	3.0	6.5
	TOTAL HOURS	880	3900	9100	300	3000	15000	2691	300	650
	CONVERSION FACTOR	950	950	1180	950	950	1180	1180	950	1180
	TOTAL OPERATIONAL FTEs	0.93	4.11	7.71	0.32	3.16	12.71	2.28	0.32	0.55

7. REMARKS  
 CFSAN will issue biannual Dioxin Schedule.  
 DSC Seafoods: See compliance program for collection details.  
 \*Includes analysis of 232 Total Diet Study Sample homogenates.

1. PROGRAM/ASSIGNMENT TITLE Pesticides and Industrial Chemicals in Domestic and Imported Foods				2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants -04							
3. PROGRAM/ASSIGNMENT CODE(S) 04004A,D, 04R833, 99R833, 04R824			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS (27.4)					
R E G I O N	6	DISTRICT/ SPECIALIZED LABORATORY		ISCs	ISAs CHEM	HIGH THROUGHPUT LABORATORY ISA CHEM	ISCs SEAFOOD	ISAs SEAFOOD CHEM			
	TOTAL FIELD			3000	2244	983	300	300			
NE	HEADQUARTERS			(b)(2)&(b)(7)(E)							
	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
WEAC											
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
SW	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
PA	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
PACIFIC REGIONAL LABORATORY- SW											
PACIFIC REGIONAL LABORATORY- NW											
HOURS PER OPERATION			1.6					7.8	6.0	1.6	7.8
TOTAL HOURS			4800					17503	5898	480	2340
CONVERSION FACTOR			950					1180	1180	950	1180
TOTAL OPERATIONAL FTEs			5.05					14.83	5.00	0.51	1.98
9. REMARKS											
ISC Seafoods: See compliance program for collection details.											
ISAs: Planned numbers based on SWID sending 40% of ISAs to ARL and 60% of ISAs to PRL-SW.											
Sample analyses exceed sample collections because some samples will be collected per unplanned assignments to be issued during the year.											

1 PROGRAM/ASSIGNMENT TITLE Chemotherapeutics in Seafood				2 PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04									
3 PROGRAM/ASSIGNMENT CODE(S) 04018		4 WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER						5. OPERATIONAL FTE POSITIONS 33.0					
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	FOREIGN INSPECTIONS	IMPORT SAMPLE COLL	IMPORT SAMPLE ANALYSIS	ISAs NITRO- FURANS	ISAs INDIVIDUAL SUBS	ISAs COMPOSITES	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE ANALYSIS	ISAs INDIVIDUAL SUBS	ISAs COMPOSITES	ISAs NITRO- FURANS	
		11	1000	1000	250	215	535	100	100	35	85	30	
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)											
	REGIONAL STAFF NEW ENGLAND NEW YORK REGIONAL LAB WEAC												
CE	REGIONAL STAFF BALTIMORE CHICAGO CINCINNATI DETROIT MINNEAPOLIS NEW JERSEY PHILADELPHIA FORENSIC CHEM CTR												
	REGIONAL STAFF ATLANTA FLORIDA NEW ORLEANS SAN JUAN REGIONAL LAB												
	REGIONAL STAFF DALLAS DENVER KANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL LAB												
	REGIONAL STAFF LOS ANGELES SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY - SW PACIFIC REGIONAL LABORATORY - NW												
	HOURS PER OPERATION	30.0	2.5	24.0	30.0			5.0	24.0				30.0
	TOTAL HOURS	330	2500	24000	7500			500	2400				900
	CONVERSION FACTOR	950	950	1180	1180			950	1180				1180
	OPERATIONAL FTEs	0.35	2.63	20.34	6.38			0.53	2.03				0.76
7 REMARKS													
<p>CFSAN spread the number of sample collections per district based on ORADSS line entry data and domestic OEI data. DFS spread the laboratory analyses. Individual sub sample analyses will be for Nitrofurans in shrimp and for all Chloramphenicol samples. All remaining residue analyses will be a composite of 12 subsamples. The analytical module is a Field Wide Average, based on number of total samples planned for individual subsample analysis and for composite analysis. Refer to the FY09 Collection Schedule (when issued) for specific commodities to collect. Import samples can be collected as D/I samples if samples are being collected fresh. The sample collection and analytical numbers are based on all products except for crab being analyzed for two chemotherapeutic agents.</p> <p>(b)(2)&amp;(b)(7)(E)</p> <p>* Import Samples for Nitrofurans include 125 Basa/Catfish samples and 125 Shrimp samples.                  ** Domestic Samples for Nitrofurans include 20 catfish and 10 shrimp samples.</p> <p>The shaded area serves as a guideline for Districts on the specific types of samples that should be collected in order to match samples expected by the laboratories for analysis.</p>													

1 PROGRAM/ASSIGNMENT TITLE Toxic Elements in Foods (Domestic and Import)			2 PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04							
3 PROGRAM/ASSIGNMENT CODE(S) 04019A			4 WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5 OPERATIONAL FTE POSITIONS 19.2 (12.5)				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	DSC NON- SEAFOOD	ISC NON- SEAFOOD	DSA NON- SEAFOOD CHEM	ISA NON- SEAFOOD CHEM	DSC <sub>s</sub> SEAFOOD	DSA <sub>s</sub> SEAFOOD CHEM	DSA <sub>s</sub> METHYL MERCURY IN SEAFOOD		
	TOTAL FIELD	25	625	25	625	310	210	100		
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY - SW									
	PACIFIC REGIONAL LABORATORY - NW									
	HOURS PER OPERATION	3.5	1.8	12.0	12.0	4.5	12.0	12.0		
	TOTAL HOURS	88	1125	300	7500	1395	2520	1200		
	CONVERSION FACTOR	950	950	1180	1180	950	1180	1180		
	TOTAL OPERATIONAL FTEs	0.09	1.18	0.25	6.38	1.47	2.14	1.02		
7 REMARKS Both Seafood and Non-Seafood Domestic and Import Sample Collections: CFSAN will issue collection schedules.										

1 PROGRAM/ASSIGNMENT TITLE Toxic Elements in Foodware (Domestic and Import)		2 PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04													
3 PROGRAM/ASSIGNMENT CODE(S) 04019B		4 WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER					5 OPERATIONAL FTE POSITIONS (5.9)								
R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	DSCs (Houseware)	ISCs (Houseware)	DOMESTIC FIELD EXAMS	IMPORT INV HOURS	DSAs CHEM	ISAs CHEM	IMPORT FIELD EXAM **							
	TOTAL FIELD	10	200	25	684	10	200	5700							
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)													
	REGIONAL STAFF														
	NEW ENGLAND														
	NEW YORK														
	REGIONAL LAB														
WEAC															
CE	REGIONAL STAFF														
	BALTIMORE														
	CHICAGO														
	CINCINNATI														
	DETROIT														
	MINNEAPOLIS														
	NEW JERSEY														
	PHILADELPHIA														
	FORENSIC CHEM CTR														
SE	REGIONAL STAFF														
	ATLANTA														
	FLORIDA														
	NEW ORLEANS														
	SAN JUAN														
REGIONAL LAB															
SW	REGIONAL STAFF														
	DALLAS														
	DENVER														
	KANSAS CITY														
	SOUTHWEST IMPORT DISTRICT														
REGIONAL LAB															
PA	REGIONAL STAFF														
	LOS ANGELES														
	SAN FRANCISCO														
	SEATTLE														
	PACIFIC REGIONAL LABORATORY - SW														
PACIFIC REGIONAL LABORATORY - NW															
HOURS PER OPERATION									3.5	1.8	0.7		10.0	10.0	0.5
TOTAL HOURS									35	360	18	684	100	2000	2850
CONVERSION FACTOR									950	950	950	950	1180	1180	950
TOTAL OPERATIONAL FTEs									0.04	0.38	0.02	0.72	0.08	1.69	3.00
7. REMARKS *IMPORT INV Hours are for field exams and any other import operations as required by the District to cover import priorities. District should report time under the appropriate operation and PAC for the activities performed. **Import field exams are to routinely include: verification that the imported product is the same as that which was declared (reconciliation exam); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc) and traditional safety concerns. These activities are to be reported as a single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of pre-determined "for cause" CT exam, or the event CT suspicions are raised conducting routine work requiring follow-up should an additional exam and time be reported under the CT PAC (03R845, 04R845, etc.) For districts that are not provided domestic field exam and sample collection resources, district should still collect samples, if necessary.															

1. PROGRAM/ASSIGNMENT TITLE Radionuclides in Foods (Domestic and Import)	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
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3. PROGRAM/ASSIGNMENT CODE(S) 04019C	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS (0.8)
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R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY			DSC	ISC			DSAs CHEM	ISAs CHEM	
				16	84			16	84	
	TOTAL FIELD			16	84			16	84	
	HEADQUARTERS			(b)(2)&(b)(7)(E)				(b)(2)&(b)(7)(E)		
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
SE	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
HOURS PER OPERATION				2.5	1.7			15.0	6.0	
TOTAL HOURS				40	143			240	504	
CONVERSION FACTOR				950	950			1180	1180	
TOTAL OPERATIONAL FTEs				0.04	0.15			0.20	0.43	

7. REMARKS

CFSAN spreads DSCs based on location of nuclear power plants. See compliance program for collection details.

1 PROGRAM/ASSIGNMENT TITLE Total Diet Study			2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04						
3 PROGRAM/ASSIGNMENT CODE(S) 04839		4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 28.6				
R E G I O N	6	DSCa (TOTAL) (DIET) (1)	DOMESTIC SAMPLE TO BE ANALYZED CHEM (2)	TOTAL DIET SAMPLE ANALYSIS (RADIONUCLIDES) CHEM (3)	TOTAL DIET SAMPLES ANALYSIS (PERCHLORATES) CHEM (4)				
	DISTRICT/ SPECIALIZED LABORATORY								
	TOTAL FIELD	60	1136	2	1136				
	HEADQUARTERS	(b)(2)&(b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
SEATTLE									
PACIFIC REGIONAL LABORATORY - SW									
PACIFIC REGIONAL LABORATORY - NW									
HOURS PER OPERATION		26.0	20.1	2800.0	3.0				
TOTAL HOURS		1560	22834	5600	3408				
CONVERSION FACTOR		950	1180	1180	1180				
TOTAL OPERATIONAL FTEs		1.64	18.35	4.75	2.89				

7 REMARKS

(1) Each DSC represents a District's weekly collection of specified food items. Each market basket collection is spread over five week period and involves 3 separate districts. Four market baskets are planned annually.

(2) Represents the total number of food items analyzed for various attributes. VOC analyses will no longer be conducted on TDS foods.

(3) All TDS food items from two market basket analyzed by WEAC for selected radionuclides.

(4) All TDS foods from each market basket are analyzed for perchlorates.







1. PROGRAM/ASSIGNMENT TITLE Outbreak and Emergency Response (PPS 04)	2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants - 04
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3. PROGRAM/ASSIGNMENT CODE(S) 04R839	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 11.9
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R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	CSO	CHEM						
		Hours Total (1)	Analyst Hours Total (2)						
TOTAL FIELD		2774	10637						
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
SE	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
SW	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
PA	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
HOURS PER OPERATION									
TOTAL HOURS		2774	10637						
CONVERSION FACTOR		950	1180						
TOTAL OPERATIONAL FTEs		2.82	9.01						

7 REMARKS  
 Time to be used for all outbreak and emergency activities related to pesticides and chemical contaminants. District spread is for planning purposes only. Report inspections and analyses conducted in response to pesticides and chemical contaminants against the appropriate Foodborne Emergency PAC (e.g. 04R853 Pet Food Emergency /Recall-Human Food Use, or another PAC to be created in response to a future emergency).



1. PROGRAM/ASSIGNMENT TITLE Mycotoxin in Domestic and Import Foods PAGE I				2. PPS PROJECT NAME/NUMBER Molecular Biology & Natural Toxins - 07							
3. PROGRAM/ASSIGNMENT CODE(S) 07001 (DOMESTIC)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> X ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS (Total 14.6) 9.3				
R E G I O N	6	DISTRICT/ SPECIALIZED LABORATORY	3 DSCs AFLA- TOXIN	3 DSCs FUMON- ISON	3 DSCs DON	3 DSCs OCHRA TOXIN	3 DSCs PATULIN	7 ALL DOMESTIC SAMPLE ANALYSES	7 DSA AFLA- TOXIN	7 DSA FUMON- ISON	7 DSA DON
	TOTAL FIELD		485	190	145	80	140	1000	485	190	145
HEADQUARTERS (b)(2)&(b)(7)(E)											
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
SW	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
PA	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
SEATTLE											
PACIFIC REGIONAL LAB - SW											
PACIFIC REGIONAL LAB - NW											
HOURS PER OPERATION			4.0	4.0	4.0	4.0	4.0	8.0			
TOTAL HOURS			1860	760	580	240	560	6000			
CONVERSION FACTOR			950	950	950	950	950	1180			
TOTAL OPERATION FTEs			1.86	0.80	0.61	0.25	0.59	5.08			

7. REMARKS

Report all Domestic and Import Operations under PAC 07001.

1 PROGRAM/ASSIGNMENT TITLE Mycotoxin in Domestic and Import Foods PAGE 2				2 PPS PROJECT NAME/NUMBER Molecular Biology & Natural Toxins - 07							
3 PROGRAM/ASSIGNMENT CODE(S) 07001 (DSA, ISCs)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> X ORA <input type="checkbox"/> CENTER				5 OPERATIONAL FTE POSITIONS 1.4				
R E G I O N	6	DISTRICT/ SPECIALIZED LABORATORY	7	7	4	4	4	4	4	4	
			DSAs OCHRA TOXIII	DSAs PATULIN	ISCs AFLA TOXIN	ISCs PEANUT BUTTER	ISCs FUMON- ISON	ISCs DON	ISCs OCHRA TOXIN	ISCs PATULIN	ISCs SPECIAL SURVEY
		TOTAL FIELD	60	140	284	(105)	90	90	40	140	20
	HEADQUARTERS (b)(2)&(b)(7)(E)										
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
SE	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
SW	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
PA	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
PACIFIC REGIONAL LAB - SW											
PACIFIC REGIONAL LAB - NW											
	HOURS PER OPERATION				2.0		2.0	2.0	2.0	2.0	2.0
	TOTAL HOURS				568		180	180	80	280	40
	CONVERSION FACTOR				950		950	950	950	950	950
	TOTAL OPERATION FTEs				0.60		0.19	0.19	0.08	0.29	0.04
7 REMARKS											

1 PROGRAM/ASSIGNMENT TITLE Mycotoxin in Domestic and Import Foods PAGE 3	2. PPS PROJECT NAME/NUMBER Molecular Biology & Natural Toxins - 07
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3 PROGRAM/ASSIGNMENT CODE(S) 07001 (ISAs)	4 WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.9
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R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	8 ALL IMPORT SAMPLE ANALYSES	8 ISAs AFLA TOXIN	8 ISAs FUMON- ISON	8 ISAs DON	8 ISAs OCHRA TOXIN	8 ISAs PATULIN	8 ISAs SPECIAL SURVEY	8 IMPORT SAMPLES TO BE ANALYZED	8 OTHER OPERAT- IONS (HOURS)									
											TOTAL FIELD	664	284	90	90	40	140	20	
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)																	
	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
WEAC																			
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
SE	FORENSIC CHEM_CTR																		
	REGIONAL STAFF																		
	ATLANTA																		
	FLORIDA																		
	NEW ORLEANS																		
SW	SAN JUAN																		
	REGIONAL LAB																		
	REGIONAL STAFF																		
	DALLAS																		
	DENVER																		
PA	KANSAS CITY																		
	SOUTHWEST IMPORT DISTRICT																		
	REGIONAL LAB																		
	REGIONAL STAFF																		
	LOS ANGELES																		
SAN FRANCISCO																			
SEATTLE																			
PACIFIC REGIONAL LAB - SW																			
PACIFIC REGIONAL LAB - NW																			
HOURS PER OPERATION											7.0								
TOTAL HOURS											4648								
CONVERSION FACTOR											1180								
TOTAL OPERATION FTEs											3.94								

7. REMARKS

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Methods Validation/Development Program	<b>2. PPS PROJECT NAME/NUMBER</b> Molecular Biology and Natural Toxins - 07
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<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 07R816	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> 4.5
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R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	METHODS VAL/DEV CHEM (Hours)	APPLIED TECHNOLOGY CENTER CHEM (Hours)	APPLIED TECHNOLOGY CENTER MICRO (Hours)					
	<b>TOTAL FIELD</b>	600	4130	600					
	HEADQUARTERS	(b)(2)&(b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
SE	FORENSIC CHEM CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
SW	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
PA	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	<b>HOURS PER OPERATION</b>								
	<b>TOTAL HOURS</b>	600	4130	600					
	<b>CONVERSION FACTOR</b>	1205	1180	1180					
	<b>TOTAL OPERATIONAL FTEs</b>	0.50	3.50	0.50					

**9. REMARKS**

Workload Source: Determined by Division of Field Science, ORO.



1 PROGRAM/ASSIGNMENT TITLE Imported Foods - Food and Color Additives				2 PPS PROJECT NAME/NUMBER Food & Color Additive Petition Review & Policy Development - 09						
3 PROGRAM/ASSIGNMENT CODE(S) 09006A (Foods), 09006B (Colors)			4 WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5 OPERATIONAL FTE POSITIONS 14.6			
R E G I O N	6	4	8	2	4	8	8	1	9	
	DISTRICT/ SPECIALIZED LABORATORY	ISCs FOOD ADDITIVES	ISAs FOOD ADDITIVES	IMPORT INVESTI- GATION HOURS **	ISCs COLOR ADDITIVES	ISAs COLOR ADDITIVES	IMPORT FIELD EXAMS	FOREIGN INSPECTIONS	OTHER OPERATIONS (Hours)	
	TOTAL FIELD	310	310	522	865	865	2800	2		
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)					(b)(2)&(b)(7)(E)			
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		1.4	13.0		1.4	10.0	0.50	30.0		
TOTAL HOURS		434	4030	522	1211	8650	1400	60		
CONVERSION FACTOR		950	1180	850	950	1180	950	950		
OPERATIONAL FTEs		0.46	3.42	0.55	1.27	7.33	1.47	0.06		

7 REMARKS

Note: Resources for Entry Review and Filer Evaluation are planned under the Import Foods - General Program (PAC 03819).

\* Import Field Exams are to routinely include: verification that the imported products are the same as that which were declared (Reconciliation Exams), an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc.), and traditional safety concerns. These activities are to be reported as a single Import Field Exam under this compliance program and PAC. Only one exam should be reported per line entry.

Only in the event of a pre-determined "for cause" CT exam, or in the event CT suspicions are raised while conducting routine work, requiring follow-up, should an additional exam and time be reported under a CT PAC (03R845, 04R845, etc.). See IOM Section 5.4.1.4.1 for additional information on Food and Cosmetic Securities Activities.

\*\* Import Investigation Hours are for label reviews of Food and Color Additives as required by Districts to cover program priorities. When repeat violations against manufacturers and importers occur, consider broad-based enforcement in lieu of continued sampling.



<b>1 PROGRAM/ASSIGNMENT TITLE</b> Retail Food Protection - State Program	<b>2 PPS PROJECT NAME/NUMBER</b> Technical Assistance: Food & Cosmetics - 18
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<b>3 PROGRAM/ASSIGNMENT CODE(S)</b> 18002	<b>4. WORK ALLOCATION PLANNED BY</b> <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> 26.0      (23.0)
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	NATIONAL RETAIL/FOOD PROGRAM STANDARDS BASELINE SUPPORT (1)	STANDARD- IZATION (ITP, CDC, IHS, STATE & LOCAL) (2)	RE-STANDARD- IZATION (ITP, STATE & LOCAL) (3)	FDA FOOD BOURNE ILLNESS RISK FACTOR STUDY (4)	TEAM LEADERS SCI/ NATIONAL (5)	NATIONAL TEAM WORK GROUP (6)	REGIONAL SEMINARS (7)	TRAINING WORKSHOPS PRE-STANDARD- IZATION TRAINING (8)	TECHNICAL ASSISTANCE (9)
	<b>TOTAL FIELD</b>	8500	1776	2048	300	1200	3380	1560	2600	6196

	HEADQUARTERS	(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DIST									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									

<b>HOURS PER OPERATION</b>										
<b>TOTAL HOURS</b>	8500	1776	2048	300	1200	3380	1560	2600	6196	
<b>CONVERSION FACTOR</b>	1200	1200	1200	1200	1200	1200	1200	1200	1200	
<b>OPERATIONAL FTEs</b>	7.08	1.48	1.71	0.25	1.00	2.82	1.30	2.17	5.16	

**7 REMARKS**  
 Report Counter Terrorism work performed only under 18RB45.

(1) Includes time for meetings, presentations, workshops, conference calls, and any other direct contact with jurisdictions to promote their enrollment in the program standards. Contact with jurisdictions to assist them with completing their self assessments, strategic plans, and verification audits performed directly by the FDA Food Specialists.

(2) Standardization of regulatory retail food inspection/training officers in the interpretation and application of the FDA Food Code and methods of conducting risk-based inspections. Continued support of the ITP Program FDA Food Specialists will be standardizing a few ITP Associate Standards.

(3) Re-standardization every three years for regulatory retail food inspection/training officers in the application of the FDA Food Code and methods in conducting risk-based inspections. Also included is the re-standardization of FDA Food Specialists by their respective Regional Associate Standard. The joint inspections required in re-standardization process may be completed in one fiscal year or spread out over a three year period.

(4) Allocation of time to work with the 2008 Risk Factor Study Design Work Group for the FDA Foodborne Illness Risk Factor Study and to collect data, data entry, quality assurance, and data analysis.

(5) Time allocated for team leaders of the National Retail Food Team Steering Committee for retail food program planning, development, and coordination.

(6) Provides time for initiatives related to the Retail Food Program development of agency procedures, guidance documents, standards, and initiative of National Importance. Includes attendance and active participation in team conference calls and face-to-face meetings/planning sessions.

(7) Includes time for preparation work, coordination, and organization, as well as, the presentation delivered in conjunction with the annual Regional Retail Food Seminars.

(8) Includes training workshops not limited to Food Code courses, pre-standardization workshops, HACCP workshops, and other identified training topics. Also, includes time for the Specialists to prepare candidates for standardization, as well as, the presentation and training sessions given to stakeholder group via conference calls, seminars, conferences, web meetings, or other means.

(9) Includes technical assistance and consultation to enrolled state and local jurisdictions performing self-assessments, and developing strategic plans using the Program Standards as the foundation for enhancing the effectiveness of their retail food programs. (CONTINUE ON PAGE 18-3, remarks)

1. PROGRAM/ASSIGNMENT TITLE Retail Food Protection - State Program				2. PPS PROJECT NAME/NUMBER Technical Assistance: Food & Cosmetics - 18					
3. PROGRAM/ASSIGNMENT CODE(S) 18002		4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS (3.0)			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	CONFERENCE FOR FOOD PROTECTION ACTIVITIES (10)	FOOD DEFENSE OTHER & CFSAN DIRECTED PROJECTS (11)						
	TOTAL FIELD	2600	1040						
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
WEAC									
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
PA	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LAB - SW								
PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION									
TOTAL HOURS				2800	1040				
CONVERSION FACTOR				1200	1200				
OPERATIONAL FTEs				2.17	0.87				

7. REMARKS Continued

Also includes interpretations and consultations on the Food code and other food safety issues. Also includes planning and field activities related to food safety and security events working in conjunction with other federal agencies.

(10) Includes all committee work for the Conference for Food Protections and preliminary work on issues/position paper development for 2008 CFP.

(11) Time allocated for the presentation and distribution of FDA materials related to food defense, such as guidance document, "Retail Food Stores and Food Service Establishments: Food Security Preventive Measures," to state and local regulatory agencies and industry. Includes counter-terrorism presentations at seminars, meetings, conferences, etc. Also includes Specialist' activities related to CFSAN priority assignments in response to national food safety needs.

<b>1. PROGRAM/ASSIGNMENT TITLE</b> (NCIMS) Milk Safety Program	<b>2. PPS PROJECT NAME/NUMBER</b> Technical Assistance: Food & Cosmetics - 18
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<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 18003	<b>4. WORK ALLOCATION PLANNED BY</b> <div style="display: flex; justify-content: space-around;"> <span><input type="text"/> ORA</span> <span><input checked="" type="checkbox"/> CENTER</span> </div>	<b>5. OPERATIONAL FTE POSITIONS</b> 20.4 (18.1)
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	CHECK RATING PLANT <sup>1</sup>	CHECK RATING TRANSFER AND RECEIVING <sup>1</sup>	CHECK RATING BTU <sup>1</sup>	SINGLE SERVICE AUDITS <sup>1</sup>	STATE MILK SANITATION RATING OFF. INITIAL/CONT CERTIFICA- TION <sup>2</sup>	TECHNICAL ASSISTANCE HOURS	STATE PROGRAM EVALUATIONS <sup>3</sup>	STATE MILK SAMPLING OFFICER INITIAL CONT <sup>1</sup>	NATIONAL STEERING TEAM CONFERENCE CALLS/TEAM <sup>4</sup>
	TOTAL FIELD	158	41	294	75	37	51	17	33	26

	HEADQUARTERS	(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTR									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW										

HOURS PER OPERATION	24.0	12.0	20.0	8.0	40.0	100.0	120.0	24.0	60.0
TOTAL HOURS	3792	492	5880	600	1480	5100	2040	792	1560
CONVERSION FACTOR	1200	1200	1200	1200	1200	1200	1200	1200	1200
OPERATIONAL FTEs	3.16	0.41	4.90	0.50	1.23	4.25	1.70	0.66	1.30

**7. REMARKS**

1/ Check Ratings of Plants and RS/TS Every 3 Years, BTUs Every 4 Years and Audits Every 5 Years

2/ Activities Include the Initial (Including HACCP) and Continuous Certifications of State Rating Officers and Sampling Surveillance Officers.

3/ State Program Evaluations Conducted of 1/3 of the States (Including Puerto Rico) Every 3 Years.

4/ Activities Include the National Steering Team Meetings and conference calls and time for team leader activities ( 2 RMSs with an additional 240 hours each identified).

1. PROGRAM/ASSIGNMENT TITLE (NCIMS) Milk Safety Program				2. PPS PROJECT NAME/NUMBER Technical Assistance: Food & Cosmetics - 18															
3. PROGRAM/ASSIGNMENT CODE(S) 18003			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS (2.3)												
R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	RMS STANDARDI- ZATION <sup>5</sup>	FOOD DEFENSE COORDINATION <sup>6</sup>	TRAINING GIVEN <sup>7</sup>															
					TOTAL FIELD	12	20	31											
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)																	
	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
WEAC																			
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
	FORENSIC CHEM. CTR																		
SE	REGIONAL STAFF																		
	ATLANTA																		
	FLORIDA																		
	NEW ORLEANS																		
	SAN JUAN																		
SW	REGIONAL LAB																		
	REGIONAL STAFF																		
	DALLAS																		
	DENVER																		
	KANSAS CITY																		
PA	SOUTHWEST IMPORT DISTRICT																		
	REGIONAL LAB																		
	REGIONAL STAFF																		
	LOS ANGELES																		
	SAN FRANCISCO																		
	SEATTLE																		
PACIFIC REGIONAL LAB - SW																			
PACIFIC REGIONAL LAB - NW																			
HOURS PER OPERATION											40.0	20.0	60.0						
TOTAL HOURS											480	400	1860						
CONVERSION FACTOR											1200	1200	1200						
OPERATIONAL FTEs											0.40	0.33	1.55						

7 REMARKS Continued

5/ Activities include the Re-standardization (Group Field Exercise) of the RMS

6/ Includes time for presentation and distribution of the food defense preventive measures guidance document for dairy products to the state regulatory agencies during check ratings routine field work and state program assessments. Presentations may be made at regional seminars or local meetings and included in training sessions for all segments of the regulatory and industry community. Coordination of food defense activities and field activities related to food defense. Report time against PAC 18R845.

7/ Activities include the Regional Milk Seminar/SST Training Courses/Regional Training/Workshops and RMS Teaching Cadre.

1. PROGRAM/ASSIGNMENT TITLE <b>Molluscan Shellfish Evaluation Program</b>	2. PPS PROJECT NAME/NUMBER <b>Technical Assistance: Food &amp; Cosmetics - 18</b>
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3. PROGRAM/ASSIGNMENT CODE(S) <b>18004</b>	4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS <b>14.7      (12.6)</b>
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	GROWING AREA EVALUATION  (1)	CONTROL OF HARVEST  (2)	VIBRO SPECIES MANAGE- MENT (HOURS) (3)	TECHNICAL ASSISTANCE (HOURS) (4)	FOREIGN EVALUATION  (5)	NATIONAL TEAM REPS  (6)	TRAINING WORKSHOPS  (7)	PLANT EVALUATION  (8)	STANDARD- IZATION & RE-STANDARD- IZATION (9)
	<b>TOTAL FIELD</b>	<b>180</b>	<b>22</b>	<b>1900</b>	<b>4040</b>	<b>4</b>	<b>2</b>	<b>14</b>	<b>125</b>	<b>14</b>

	HEADQUARTERS	(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM CTR									
	REGIONAL STAFF									
SE	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTR									
PA	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW										

HOURS PER OPERATION	20.0	90.0			200.0	180.0	30.0	10.0	40.0
TOTAL HOURS	3800	1950	1900	4040	800	360	420	1250	560
CONVERSION FACTOR	1200	1200	1200	1200	1200	1200	1200	1200	1200
OPERATIONAL FTEs	3.17	1.65	1.58	3.37	0.67	0.30	0.35	1.04	0.47

7 REMARKS

(1) Time is allocated for planning, field evaluations, file reviews (Comprehensive Growing Area Sanitary Surveys, Triennial Evaluations and Annual Updates) growing area data reviews and report writing to determine state program conformity to the requirements of the National Shellfish Sanitation Program (NSSP) Model Ordinance (MO). The overwhelming majority of shellfish related illnesses have been attributed to shellfish contamination due to conditions in the shellfish growing areas.

(2) Time is allocated for planning, field evaluations, file reviews, growing area data reviews and report writing to determine state program conformity MO. illnesses and outbreaks have been attributed to the illegal harvest of shellfish from closed waters.

(3) Activities include technical assistance, education, and evaluation of state shellfish programs *Vibrio vulnificus* and *vibrio parahaemolyticus* and management programs.

(4) Includes interpretations and consultation on NSSP MO requirements related to program administration, risk management, laboratory, shellfish areas, shell stock relaying, shellfish aquaculture, shellfish wet storage and depuration, patrol, shellfish harvest and transportation, HACCP, and general sanitation in processing plants.

(5) Activities include planning, field evaluations, file reviews, and report writing for countries with MOUs with the FDA. Current MOU countries include Canada, Chile, South Korea, Mexico, and New Zealand.

(6) Includes time for shellfish program planning, development and coordination responsibilities assigned to two specialists selected as team representatives of the Regional Shellfish Specialists' team.

(7) Includes training workshops coordinated and delivered by the specialists, including but not limited to basic shellfish plant and program courses applied concepts for shellfish growing areas courses and HACCP workshops.

(8) Includes time for planning, field evaluations of processing plants, file reviews, and final report writing to determine state conformity with the NSSP MO. Plant full evaluation of HACCP, including plan implementation and adherence to the sanitation requirements of the NSSP MO.

(9) Standardization conducted every 5 years for all FDA and state standardization officers. (CONTINUED ON PAGE 18 -4, remarks)

1. PROGRAM/ASSIGNMENT TITLE Moulluscan Shellfish Evaluation Program			2. PPS PROJECT NAME/NUMBER Technical Assistance: Food & Cosmetics - 18								
3. PROGRAM/ASSIGNMENT CODE(S) 18004		4. WORK ALLOCATION PLANNED BY ORA <input type="checkbox"/> CENTER <input checked="" type="checkbox"/>			5. OPERATIONAL FTE POSITIONS (2.1)						
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	NATIONAL TEAM WORKSHOP (10)	CENTER INITIA- TIVES/LAB (11)	REGIONAL SEMINARS (12)	FOOD DEFENSE COORDINATION (13)	ISSC COMMITTEE (14)					
	TOTAL FIELD	11	7	12	11	13					
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)									
	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
WEAC											
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM. CTR										
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
SW	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
PA	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
SEATTLE											
PACIFIC REGIONAL LAB - SW											
PACIFIC REGIONAL LAB - NW											
HOURS PER OPERATION							40.0	40.0	30.0	20.0	90.0
TOTAL HOURS							440	280	360	220	1170
CONVERSION FACTOR							1200	1200	1200	1200	1200
OPERATIONAL FTEs							0.37	0.23	0.30	0.18	0.98

7. REMARKS Continued

Re-standardization training will be provided during evaluation and technical assistance work while working in shellfish processing plants with state and FDA SSOs.

(10) Includes specialist initiatives related to shellfish program development of agency procedures, guidance documents, standards, and initiatives of national importance includes discussions of FDA issues for the ISSC agency program priorities, etc.

(11) Time allocated for CFSAN priority assignments in response to national shellfish safety. Time is also allocated for the specialists to assist the FDA Laboratory Evaluation Officer (LEO) in the planning and evaluation activities of state shellfish program labs.

(12) Includes time for the Regional Shellfish Specialists to attend regional shellfish conferences, Pacific Rim Shellfish Conference, Gulf and South Atlantic States Shellfish Conference, Interstate Seafood Seminar and the Northeast Shellfish Sanitation Conference.

(13) Time allocated for presentation and distribution of the Food Producers, Processors, and Transporter: Food Security Preventive Measures Guidance to the state regulatory agencies and industries during field work and state program evaluations. Presentations may be made at regional seminars or local meetings and presentations may also be included in training sessions for all segments of the regulatory and industry community.

(14) Time allocated for the specialists to attend the biennial Interstate Shellfish Sanitation Conference to address program related issues and new ISSC proposals. Represent FDA on ISSC committees, task forces and work groups. Prior to the conference FDA receives the submitted issue that will serious burden upon FDA to consider the issues as submitted and to formulate agency-approved scientific and policy positions that will be communicated at the meeting.

1 PROGRAM/ASSIGNMENT TITLE Interstate Travel Program - Conveyances and Support Facilities				2 PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18						
3 PROGRAM/ASSIGNMENT CODE(S) 18029 A - F			4 WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5 OPERATIONAL FTE POSITIONS 21.8 (21.5)			
R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	INSP ECTIONS (%)	CONVEY UNDER CONSTRUCTION HOURS (*)	WATERING POINTS INSP (A) (**)	CATERING POINTS INSP (B) (**)	CONVEYANCE INSP (C)	AIRLINE WATERING POINTS INSP (D)	DSCs MICRO SURV	DSA MICRO	INV (HOURS)
	TOTAL FIELD	1555	1360	(283)	(492)	(259)	(319)	180	180	900
N E	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
N E	NEW ENGLAND	(b)(2)&(b)(7)(E)								
	NEW YORK	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	WEAC	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
C E	BALTIMORE	(b)(2)&(b)(7)(E)								
	CHICAGO	(b)(2)&(b)(7)(E)								
	CINCINNATI	(b)(2)&(b)(7)(E)								
	DETROIT	(b)(2)&(b)(7)(E)								
	MINNEAPOLIS	(b)(2)&(b)(7)(E)								
	NEW JERSEY	(b)(2)&(b)(7)(E)								
	PHILADELPHIA	(b)(2)&(b)(7)(E)								
	FORENSIC CHEM. CTR	(b)(2)&(b)(7)(E)								
S E	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	ATLANTA	(b)(2)&(b)(7)(E)								
	FLORIDA	(b)(2)&(b)(7)(E)								
	NEW ORLEANS	(b)(2)&(b)(7)(E)								
	SAN JUAN	(b)(2)&(b)(7)(E)								
S W	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	DALLAS	(b)(2)&(b)(7)(E)								
	DENVER	(b)(2)&(b)(7)(E)								
	KANSAS CITY	(b)(2)&(b)(7)(E)								
P A	SOUTHWEST IMPORT DISTRICT	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	LOS ANGELES	(b)(2)&(b)(7)(E)								
	SAN FRANCISCO	(b)(2)&(b)(7)(E)								
P A	SEATTLE	(b)(2)&(b)(7)(E)								
	PACIFIC REGIONAL LAB - SW	(b)(2)&(b)(7)(E)								
	PACIFIC REGIONAL LAB - NW	(b)(2)&(b)(7)(E)								
HOURS PER OPERATION		10.5						4.0	8.0	
TOTAL HOURS		16328	1360					720	1440	900
CONVERSION FACTOR		950	950					950	1180	950
TOTAL OPERATIONAL FTEs		17.19	1.43					0.76	1.22	0.95
7. REMARKS:  (%) Inspections in Columns A-D are included in Column 1. The additional inspections can be used on other establishments under the program. Time is allocated for Food Code promotion, coverage of Food Security issues and completion of Application of Food Code, Attachment B. DSCs should be randomly collected from on-board conveyances water systems outlets ex. faucets, as close to the water holding tank as possible. (*)Time for Conveyance under Construction- time to be used for plan review, meetings, and final inspections It includes galleys in DAL, LOS and Aircraft/Vessels in SAN & SEA. (**)Catering Point Insp. (B) is High Risk Priority and some potential Food Allergen firms identified by the District. (***) all other watering points										

1 PROGRAM/ASSIGNMENT TITLE Interstate Travel Program - Conveyances and Support Facilities	2 PPS PROJECT NAME/NUMBER Technical Assistance: Food and Cosmetics - 18
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3 PROGRAM/ASSIGNMENT CODE(S) 18029 A - F	4 WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS (0.3)
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R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	DSCs CHEM for CAUSE (***)	DSAs CHEM								
	TOTAL FIELD	20	20								
	HEADQUARTERS	(b)(2)&(b)(7)(E)									
NE	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
	WEAC										
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
	FORENSIC CHEM CTR										
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
SW	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
PA	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LAB - SW										
	PACIFIC REGIONAL LAB - NW										
	HOURS PER OPERATION	4.0	12.0								
	TOTAL HOURS	80	240								
	CONVERSION FACTOR	950	1180								
	TOTAL OPERATIONAL FTEs	0.08	0.20								

7 REMARKS:  
 (\*\*\*\*)Includes water sample collected from conveyances under construction and major reconstruction to determine compliance with EPA's National Drinking Water Standards (40 CFR 141 & 142) regarding Maximum Contaminant Levels (NCLs) for heavy metals (Pb,Cu, etc.)



1. PROGRAM/ASSIGNMENT TITLE Medical Foods - Domestic and Import	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
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3. PROGRAM/ASSIGNMENT CODE(S) 21002	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.7
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	7	7	8	8
		INSP CTIONS	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL CHEM	DOMESTIC SAMPLE COLL MICRO	IMPORT SAMPLE COLL	DSAs MICRO	DSAs CHEM	ISAs CHEM	Foreign Inspection
	TOTAL FIELD	18	36	20	16	8	16	20	8	2

HEADQUARTERS		(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	NEW ENGLAND	(b)(2)&(b)(7)(E)								
	NEW YORK	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	WEAC	(b)(2)&(b)(7)(E)								
CE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	BALTIMORE	(b)(2)&(b)(7)(E)								
	CHICAGO	(b)(2)&(b)(7)(E)								
	CINCINNATI	(b)(2)&(b)(7)(E)								
	DETROIT	(b)(2)&(b)(7)(E)								
	MINNEAPOLIS	(b)(2)&(b)(7)(E)								
	NEW JERSEY	(b)(2)&(b)(7)(E)								
	PHILADELPHIA	(b)(2)&(b)(7)(E)								
	FORENSIC CHEM. CTR	(b)(2)&(b)(7)(E)								
SE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	ATLANTA	(b)(2)&(b)(7)(E)								
	FLORIDA	(b)(2)&(b)(7)(E)								
	NEW ORLEANS	(b)(2)&(b)(7)(E)								
	SAN JUAN	(b)(2)&(b)(7)(E)								
SW	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	DALLAS	(b)(2)&(b)(7)(E)								
	DENVER	(b)(2)&(b)(7)(E)								
	KANSAS CITY	(b)(2)&(b)(7)(E)								
PA	SOUTHWEST IMPORT DISTRICT	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	LOS ANGELES	(b)(2)&(b)(7)(E)								
	SAN FRANCISCO	(b)(2)&(b)(7)(E)								
SEATTLE	(b)(2)&(b)(7)(E)									
PACIFIC REGIONAL LABORATORY - SW	(b)(2)&(b)(7)(E)									
PACIFIC REGIONAL LABORATORY - NW	(b)(2)&(b)(7)(E)									

HOURS PER OPERATION	30.0	6.0			6.0	30.0	100.0	100.0	30.0
TOTAL HOURS	540	216			48	480	2000	800	60
CONVERSION FACTOR	950	950			950	1180	1180	1180	950
TOTAL OPERATIONAL FTEs	0.57	0.23			0.05	0.41	1.69	0.68	0.06

7. REMARKS

CFSAN spread inspections and DSCs. CFSAN/OC/CPB will issue an inspection and sample collection schedule to participating districts at the beginning of each fiscal year.

ORA spreads import operations.

Time to investigate import entries for admissibility is planned under the Imports Foods General Program (7303.819)

\*Includes samples resulting from import entry review as well as samples collected during foreign inspections.

\*\*May be used for microbiological analysis.

1. PROGRAM/ASSIGNMENT TITLE Domestic Food Labeling and Economics Program	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
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3. PROGRAM/ASSIGNMENT CODE(S) 21003	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.1
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R E G I O N	b. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	4	5	7	7	8	8
		INV HOURS	DSC			DSA				
	<b>TOTAL FIELD</b>	<b>950</b>	<b>100</b>			<b>100</b>				
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)				(b)(2)&(b)(7)(E)				
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY - SW									
	PACIFIC REGIONAL LABORATORY - NW									
HOURS PER OPERATION			4.2			19.0				
TOTAL HOURS		950	420			1900				
CONVERSION FACTOR		950	950			1180				
TOTAL OPERATIONAL FTEs		1.00	0.44			1.61				

7. REMARKS  
To be issued as CFSAN Field Assignments

1. PROGRAM ASSIGNMENT TITLE Domestic and Import NLEA, Nutrient Sample/Analysis and General Food Labeling Program				2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21						
3. PROGRAM ASSIGNMENT CODE(S) 21005, 03R833, 21R824 21R829(Health Fraud)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 12.6 (6.7)			
R E G I O N	6	1	2	3	4	5	6	7	8	
	DISTRICT/SPECIALIZED LABORATORY	DSC	DSCs (DOCUMENTARY)	DSCs (PHYSICAL)	DSAs	DOMESTIC FIELD EXAMS	ISCs (PHYSICAL) OASIS #51 (SEE REMARKS) ****	ISAs	IMPORT INV HOURS (SEE REMARKS) ***	ISCs (PAPER) OASIS #41 (SEE REMARKS) *****
<b>TOTAL FIELD</b>		<b>340</b>	<b>240</b>	<b>100</b>	<b>100</b>	<b>2000</b>	<b>125</b>	<b>125</b>	<b>522</b>	<b>785</b>
N E	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF NEW ENGLAND NEW YORK REGIONAL LAB WEAC									
C E	REGIONAL STAFF BALTIMORE CHICAGO CINCINNATI DETROIT MINNEAPOLIS NEW JERSEY PHILADELPHIA FORENSIC CHEM. CTR									
	REGIONAL STAFF ATLANTA FLORIDA NEW ORLEANS SAN JUAN REGIONAL LAB									
	REGIONAL STAFF DALLAS DENVER KANSAS CITY SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
	REGIONAL STAFF LOS ANGELES SAN FRANCISCO SEATTLE PACIFIC REGIONAL LABORATORY - SW PACIFIC REGIONAL LABORATORY - NW									
	HOURS PER OPERATION	4.2			19.0	0.4	1.2	10.0		1.2
	TOTAL HOURS	1428			1900	800	150	1250	522	942
	CONVERSION FACTOR	950			1180	950	950	1180	950	950
	TOTAL OPERATIONAL FTEs	1.50			1.61	0.84	0.16	1.06	0.55	0.99
7. REMARKS										
<p>*DSCs (Physical) includes both compliance (for cause) sampling and surveillance sampling. The field should attempt to collect sufficient surveillance sample as well as needed compliance samples to meet their workplan obligations. See compliance programs for details.</p> <p>**Domestic operations to be conducted during inspections conducted under CP 7303.803,7303.803A,7303.037, 7303.842 and 7303.847. Districts should report time spent reviewing labels that does not result in a collection.</p> <p>***IMPORT INV Hours are for field exams and any other import operations as required by the district to cover import priorities. Districts should report time under the appropriate operation and PAC for the activities performed. For Import Field Exams, report time spent reviewing import labels that does not result in Import Sample Collection.</p> <p>****ISCs (Physical) includes time to collect and forward samples to the lab for analysis to support violations.</p> <p>*****ISCs (Paper) includes time spent collecting labels, records or other documentation for submission to Compliance and does not include time spent reviewing the import labels. Time spent reviewing the label will be included as OASIS #27 and reported along with compliance review time as OASIS #43. Prior to collecting product labels for trans fat and/or allergen contact CFSAN.</p>										

1. PROGRAM/ASSIGNMENT TITLE Domestic and Import NLEA, Nutrient Sample/Analysis and General Food Labeling Program			2 PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21						
3. PROGRAM/ASSIGNMENT CODE(S) 21005, 03R833, 21R824 21R829(Health Fraud)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS (5.9)		
R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	1 IMPORT FIELD EXAMS	2	3	4	5	6	7	8
	TOTAL FIELD	11200							
NE	HEADQUARTERS	(b)(2)&(b)							
	REGIONAL STAFF	(7)(E)							
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY - SW								
	PACIFIC REGIONAL LABORATORY - NW								
HOURS PER OPERATION		0.5							
TOTAL HOURS		5600							
CONVERSION FACTOR		950							
TOTAL OPERATIONAL FTEs		5.89							

7. REMARKS

All import field exams are to routinely include: verification that the imported product is the same as that which was declared (reconciliation exam), an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, and safety concerns). These activities are to be reported as a single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of pre-determined "for cause" CT exam, or in the event CT suspicions are raised conducting routine work requiring follow-up should an additional exam and time be reported under CT PAC (03R845, 04R845, etc.) See IOM Section 5.4.1.4 for additional information on Food and Cosmetic Security Activities.

1. PROGRAM/ASSIGNMENT TITLE Infant Formula - Domestic and Import	2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21
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3. PROGRAM/ASSIGNMENT CODE(S) 21006	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.6 (5.5)
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R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	1	2	3	3	2	7	7	4	8
		INSPEC- TIONS	INVESTI- GATIONS (Hours)	DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL CHEM	DOMESTIC SAMPLE COLL MICRO	DOMESTIC SAMPLES TO BE ANALYZED CHEM	DOMESTIC SAMPLES TO BE ANALYZED MICRO	IMPORT SAMPLES COLL *	IMPORT SAMPLES TO BE ANALYZED CHEM **
	TOTAL FIELD	23	200	30	20	10	20	10	15	15

NE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	42.0		5.3			100.0	120.0	5.0	100.0
	TOTAL HOURS	966	200	159			2000	1200	75	1500
	CONVERSION FACTOR	950	950	950			1180	1180	950	1180
	TOTAL OPERATIONAL FTEs	1.02	0.21	0.17			1.69	1.02	0.08	1.27

7. REMARKS

CFSAN spreads inspections and DSCs, CFSAN/OC/CPB will issue an inspection and sample collection schedule to participating districts at the beginning of each fiscal year.

ORA spreads import operations

\* Includes samples resulting from import entry review as well as samples collected during foreign inspections.

Time to investigate import entries for admissibility is planned under the Import Foods General Program (7303.819)

\*\* May also be used for microbiological analysis.

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Infant Formula - Domestic and Import		<b>2. PPS PROJECT NAME/NUMBER</b> Food Composition, Standards, Labeling and Economics - 21									
<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 21006			<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER					<b>5. OPERATIONAL FTE POSITIONS</b> (0.1)			
R E G I O N	6	1	2	3	3	3	7	7	4	8	
	DISTRICT/ SPECIALIZED LABORATORY	Foreign Inspections									
	<b>TOTAL FIELD</b>	2									
NE	HEADQUARTERS	(b)(2)& (b)(7)(E)									
	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
CE	WEAC										
	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
SE	PHILADELPHIA										
	FORENSIC CHEM. CTR										
	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
SW	NEW ORLEANS										
	SAN JUAN										
	REGIONAL LAB										
	REGIONAL STAFF										
	DALLAS										
PA	DENVER										
	KANSAS CITY										
	SOUTHWEST IMPORT DISTRICT										
	REGIONAL LAB										
	REGIONAL STAFF										
	LOS ANGELES										
SAN FRANCISCO											
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
	PACIFIC REGIONAL LABORATORY-NW										
	HOURS PER OPERATION	42.0									
	TOTAL HOURS	84									
	CONVERSION FACTOR	950									
	TOTAL OPERATIONAL FTEs	0.09									
<b>7. REMARKS</b>											

1 PROGRAM/ASSIGNMENT TITLE Dietary Supplements - Domestic and Import				2. PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21						
3 PROGRAM/ASSIGNMENT CODE(S) 21008			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 22.2 (17.9)			
R E G I O N	B DISTRICT/ SPECIALIZED LABORATORY	I INSPEC- TIONS	D DOMESTIC FIELD EXAMS	D DOMESTIC SAMPLE COLLECTION	D DOMESTIC SAMPLE ANALYZED	H HQ INIT. DOMESTIC SAMPLE COLL	H HQ INIT. DOMESTIC SAMPLE ANAL.	I INV HOURS	I ISC PAPER OASIS #41	I ISC PHYSICAL
	TOTAL FIELD	250	400	200	100	50	50	2000	360	70
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	40.0	0.5	4.2	25.0	4.2	25.0		1.6	1.6
	TOTAL HOURS	10000	200	840	2500	210	1250	2000	576	112
	CONVERSION FACTOR	950	950	950	1180	950	1180	950	950	950
	TOTAL OPERATIONAL FTEs	10.53	0.21	0.88	2.12	0.22	1.06	2.11	0.61	0.12
7 REMARKS										
<p>Field Exams and sample collections may be conducted at packers/repackers, distributors, or warehouses if the levels planned cannot be performed during the inspections.</p> <p>Investigational hours are planned primarily for CFSAN directed assignments.</p> <p>Import resources planned in page 2.</p> <p>*Half of the planned samples are physical and other half are documentary samples</p> <p>**Physical samples collected and forwarded to the laboratory for analyses to support violations.</p> <p>***Time spent collecting labels, records, or other documentation for submission to Compliance. Does not include time spent reviewing the import labels. Field Exams Time spent reviewing the label will be included as OASIS # 27 and reported along with compliance review time as OASIS #43.</p>										

1 PROGRAM/ASSIGNMENT TITLE Dietary Supplements - Domestic and Import			2 PPS PROJECT NAME/NUMBER Food Composition, Standards, Labeling and Economics - 21			
3 PROGRAM/ASSIGNMENT CODE(S) 21008		4 WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5 OPERATIONAL FTE POSITIONS (4.3)	
REGION	DISTRICT/ SPECIALIZED LABORATORY	IMPORT INV HOURS	ISA PHYSICAL CHEM	IMPORT FIELD EXAMS	FOREIGN INSPECTION	
	TOTAL FIELD	865	70	2800	10	
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)				
	REGIONAL STAFF					
	NEW ENGLAND					
	NEW YORK					
	REGIONAL LAB					
CE	WEAC					
	REGIONAL STAFF					
	BALTIMORE					
	CHICAGO					
	CINCINNATI					
	DETROIT					
	MINNEAPOLIS					
	NEW JERSEY					
SE	PHILADELPHIA					
	FORENSIC CHEM CTR					
	REGIONAL STAFF					
	ATLANTA					
	FLORIDA					
SW	NEW ORLEANS					
	SAN JUAN					
	REGIONAL LAB					
	REGIONAL STAFF					
	DALLAS					
PA	DENVER					
	KANSAS CITY					
	SOUTHWEST IMPORT DISTRICT					
	REGIONAL LAB					
	REGIONAL STAFF					
LOS ANGELES						
SAN FRANCISCO						
SEATTLE						
PACIFIC REGIONAL LABORATORY-SW						
PACIFIC REGIONAL LABORATORY-NW						
HOURS PER OPERATION			25.0	0.5	40.0	
TOTAL HOURS		865	1750	1400	400	
CONVERSION FACTOR		950	1180	950	950	
TOTAL OPERATIONAL FTEs		0.91	1.48	1.47	0.42	

7 REMARKS

\* IMPORT INV Hours are for any other import operations as required by the District to cover import priorities. Districts should report time under the appropriate operation and PAC for the activities performed. Field Exams are time spent reviewing labels that do not result in a sample collection.

\*\*All import field exams are to routinely include verification that the imported product is the same as that which was declared (reconciliation exams); and assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc) and traditional safety concerns. These activities are reported as a single import field exam under this compliance program and PAC. Only one exam should be reported per line entry. Only in the event of a pre-determined "for cause" CT exam, or in the event suspicious are raised conducting routine work requiring follow-up, should be an additional exam and time be reported under the CT PAC (03R845, 04R845, etc.) See IOM for additional information on Food and Cosmetic Defense activities.



<b>1 PROGRAM/ASSIGNMENT TITLE</b> Methods Validation/Development Program	<b>2 PPS PROJECT NAME/NUMBER</b> Food Composition, Standards, Labeling and Economics - 21
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<b>3 PROGRAM/ASSIGNMENT CODE(S)</b> 21R816	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	<b>5 OPERATIONAL FTE POSITIONS</b> 1.5
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R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	METHODS VAL/DEV CHEM (Hours)	APPLIED TECHNOLOGY CENTER CHEM (Hours)							
	<b>TOTAL FIELD</b>	<b>600</b>	<b>1180</b>							
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	<b>HOURS PER OPERATION</b>									
	<b>TOTAL HOURS</b>	<b>600</b>	<b>1180</b>							
	<b>CONVERSION FACTOR</b>	<b>1205</b>	<b>1180</b>							
	<b>TOTAL OPERATIONAL FTEs</b>	<b>0.50</b>	<b>1.00</b>							

**9. REMARKS**

Workload Source: Determined by Division of Field Science, ORO.



1. PROGRAM/ASSIGNMENT TITLE Cosmetics: Domestic and Imports				2. PPS PROJECT NAME/NUMBER Colors and Cosmetics Technology - 29						
3. PROGRAM/ASSIGNMENT CODE(S) 29001, 29R833, 29R824, 99R833		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 7.6			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPECT- IONS	2 DOMESTIC INVESTI- GATIONS (HOURS)	3 DOMESTIC SAMPLE COLL	7 DOMESTIC SAMPLE ANALYSIS (MICRO)	IMPORT INVESTI- GATIONS (HOURS)	FOREIGN INSP	4 IMPORT SAMPLE COLL 50% CHEM, 50% MICRO	8 IMPORT SAMPLE ANALYSIS (CHEM)	8 IMPORT SAMPLE ANALYSIS (MICRO)
	TOTAL FIELD		100		60	60	1000	5	230	115
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)	(b)(2)&(b)(7)(E)							
	REGIONAL STAFF	(b)(2)&(b)(7)(E)	(b)(2)&(b)(7)(E)							
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION		17.0		4.4	18.0		17.0	1.5	18.0	16.0
TOTAL HOURS		1700		264	1080	1000	85	345	1840	1840
CONVERSION FACTOR		950		950	1180	950	950	950	1180	1180
OPERATIONAL FTEs		1.79		0.28	0.92	1.05	0.09	0.36	1.56	1.58

7. REMARKS

\* Import Investigation Hours: resources are for Import Field Exams, Import Filer Evaluations and Follow-up to refusals.

All Import Field Exams are to routinely include: verification that the imported product is the same as that which was declared (Reconciliation Exam); an assessment of security concerns related to labeling and source country (including container integrity, signs of intentional adulteration, etc.); and traditional safety or label concerns. These activities are to be reported as single import field exam or label review under this compliance program and PAC. ONLY one exam should be reported per line entry.

ONLY in the event of a Pre-Determined "for cause" CT exam, or in the event that CT suspicions are raised while conducting routine work requiring follow-up should an additional exam and time be reported under the CT PAC 29R845. See IOM Section 5.4.1.4.1 for additional information on Food and Cosmetic Security Activities.

Note: If the Center initiates any assignments to follow up on drug claims on cosmetics, the field resources will be taken from this program.

**CENTER FOR BIOLOGICS EVALUATION AND RESEARCH  
RESOURCE SUMMARY  
FY 2010**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
		DOMESTIC	IMPORT	FOREIGN	
	<b>TOTAL</b>	<b>110.8</b>	<b>3.5</b>	<b>6.7</b>	<b>121.0</b>
41	HUMAN CELLULAR, TISSUE AND GENE THERAPIES	28.5		1.4	29.9
42	BLOOD AND BLOOD PRODUCTS	71.8	3.5	2.6	77.9
45	VACCINES AND ALLERGENIC PRODUCTS	10.5		2.7	13.2



1. PROGRAM/ASSIGNMENT TITLE Inspection of Human Cells, Tissues, and Cellular & Tissue-Based Products (HCT/Ps)				2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue and Gene Therapies - 41						
3. PROGRAM/ASSIGNMENT CODE(S) 41002B, C, D *		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 25.5				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC INSPEC- TIONS	2 CBER PRIORITY ESTAB *	1 FOREIGN INSPEC- TIONS	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	8 OTHER OPERATIONS (Hours)
	TOTAL FIELD		543	(118)	13					
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
	REGIONAL STAFF									
CE	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
SE	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
SW	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW										
HOURS PER OPERATION		42.2		100.0						
TOTAL HOURS		22915		1300						
CONVERSION FACTOR		950		950						
TOTAL OPERATIONAL FTES		24.12		1.37						

9. REMARKS

\* Refer to CBER's memo for inspectional priorities.

C.P. 7341.002 - Inspection of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)  
(covers HCT/Ps recovered on or after 5/25/2005)

C.P. 7341.002A - Inspection of Tissue Establishments (covers human tissue recovered before 5/25/2005)

PAC 41002B for Product Codes: 57K Reproductive Tissue  
PAC 41002C for Product Codes: 57M Hematopoietic Stem Cells  
PAC 41002D for Product Codes: 57J Musculoskeletal Tissue; 57 L Ocular Tissue;  
57 O Other Tissue (human skin, pericardium, dura mater, heart valves)

Starting in FY2010 ALL AIDS time will be reported under the appropriate Compliance Program and PAC.  
There will be NO separate reporting of AIDS time.

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE GLPs, IRBs, Sponsor/Monitor/CROs, Clinical Investigators (PDUFA Domestic & Foreign)	2. PPS PROJECT NAME/NUMBER Human Cellular, Tissue & Gene Therapies - 41
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3. PROGRAM/ASSIGNMENT CODE(S) 41808-GLP, 41809-IRB, 41810-Spon/ Mon/CROs, 41811 Clinical Investigator*	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.4
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS *	2 DOMESTIC INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>52</b>								
NE	HEADQUARTERS	(b)(2)&(b)								
	REGIONAL STAFF	(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	80.4								
	TOTAL HOURS	4181								
	CONVERSION FACTOR	950								
	TOTAL OPERATIONAL FTES	4.40								

9. REMARKS

\* Resources for PACs 41808, 41809, 41810, and 41811 are planned under PAC 41811 Clinical Investigators. Use above resources for Foreign Inspections as needed. Inspections are to be conducted only when assignments are received from CBER. Report accomplishment hours under appropriate PAC. Report Foreign Inspections under Operation Code 11.

Personnel Types Required: Investigator



1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed and Unlicensed Blood Banks (Domestic & Foreign)				2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42						
3. PROGRAM/ASSIGNMENT CODE(S) 42001F,G,A (1)		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 53.5				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC BLOOD BANK INSPEC- TIONS (2)	1	2 DOMESTIC INVESTI- GATIONS (Hours) (3)	1 FOREIGN BLOOD BANK INSPIC- TIONS (4)	1 PRE-LICENSE INSPECTIONS DOMESTIC	1 PRE-LICENSE INSPECTIONS FOREIGN	9 TECH ASST & COORDIN- ATION (Hours) OP CODE 92 (5)	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	1100		2489	10			2050		
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)				(b)(2)&(b)(7)(E)		
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		41.0			43.4					
TOTAL HOURS		45100		2489	434			2850		
CONVERSION FACTOR		950		950	950			950		
TOTAL OPERATIONAL FTEs		47.47		2.60	0.46			3.00		

7 REMARKS

- (1) All listed resources are planned under PAC 42001F. Resources cover all facilities listed in compliance program. Blood Bank PAC's: 42001F, Level 1 Inspection, 42001G, Level 2 Inspection. Pre-License Inspections for PPS 41, 42, 45 and Field Investigation Hours are not planned separately; use above resources as needed, at district discretion.
- (2) Domestic Blood Bank Inspections: Module Includes Time for AIDS. Starting in FY10 ALL AIDS time will be reported under the appropriate Compliance Program and PAC. There will be NO separate reporting of AIDS time.
- (3) Domestic Investigative Time is for National Expert Domestic Investigations and Follow-Up Inspections and may be used as needed for other CBER programs.
- (4) Foreign Blood Bank Inspections spread by DFI.
- (5) Technical Assistance & Coordination (Hours) are for BLT-DO; report time under Operation Code 92.

Refer to CBER's memo for inspectional priorities.

Personnel Types Required: Investigator, National Experts

1. PROGRAM/ASSIGNMENT TITLE Inspection of Source Plasma Establishments	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42002F,G,A *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 10.9
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	6. DISTRICT/SPECIALIZED LABORATORY	1. INSPECTIONS	2. INVESTIGATIONS (Hours)	3. DOMESTIC SAMPLE COLL	4. IMPORT SAMPLE COLL	5. FIELD EXAMS/TESTS	6. IMPORT FIELD EXAMS	7. DOMESTIC SAMPLES TO BE ANALYZED	8. IMPORT SAMPLES TO BE ANALYZED	9. OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>	<b>224</b>	<b>510</b>							
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW										
<b>HOURS PER OPERATION</b>		<b>43.8</b>								
<b>TOTAL HOURS</b>		<b>9811</b>	<b>510</b>							
<b>CONVERSION FACTOR</b>		<b>950</b>	<b>950</b>							
<b>TOTAL OPERATION FTEs</b>		<b>10.33</b>	<b>0.54</b>							

7. REMARKS

\* The above resources are planned under PAC 42002F, use resources as needed to accomplish this compliance program. Resources may be used for Domestic/Foreign/Follow-up Inspections/Investigations, DSCs as needed. Report operations under appropriate PAC and Operation Code.

Refer to CBER's memo for inspectional priorities.

Starting in FY2010 ALL AIDS time will be reported under the appropriate Compliance Program and PAC. There will be NO separate reporting of AIDS time.

Personnel Types Required: Investigator, Team Biologics

1. PROGRAM/ASSIGNMENT TITLE <b>Imported CBER-Regulated Products</b>	2. PPS PROJECT NAME/NUMBER <b>Blood and Blood Products - 42</b>
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3. PROGRAM/ASSIGNMENT CODE(S) <b>42007, 42R833, 42R824, 99R833 41R824, 45R824</b>	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS <b>3.5</b>
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 IMPORT INVESTI- GATION HOURS	3 DOMESTIC INVESTI- GATIONS (HOURS)	4 IMPORT INVESTI- GATIONS (HOURS)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>		<b>3325</b>							
NE	HEADQUARTERS		(b)(2)&(b) (7)(E)							
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - NW									
	PACIFIC REGIONAL LAB - SW									
HOURS PER OPERATION										
TOTAL HOURS			3325							
CONVERSION FACTOR			950							
TOTAL OPERATION FTES			3.50							

9. REMARKS

\* ALL Resources are planned under PAC 42007, as Import Investigation Hours.  
 Report Accomplishments under Appropriate PAC and Operation.  
 Planned Resources are to Cover ALL Import Operations: 42R833 Entry Review; 41R824, 42R824, 45R824 Follow-Up to Refusals; 99R833 Filer Evaluation, Import Investigation Hours Op 14, and any inspections needed for PAC 42007.

Note: C.P. 7342.007 "Imported CBER-Regulated Products," and Addendum "Imported Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" provides product specific guidance.

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Viral Marker Test Kits	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42008, A Domestic & Foreign *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 2.5
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	3	4	5	6	7	8	9							
		Post-Licensed DOMESTIC INSPEC- TIONS	Post-Licensed FOREIGN INSPEC- TIONS	DOMESTIC INV (Hours)	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)							
	<b>TOTAL FIELD</b>	<b>10</b>	<b>2</b>	<b>475</b>													
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)															
	REGIONAL STAFF																
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
	WEAC																
CE	REGIONAL STAFF	(b)(2)&(b)(7)(E)															
	BALTIMORE																
	CHICAGO																
	CINCINNATI																
	DETROIT																
	MINNEAPOLIS																
	NEW JERSEY																
	PHILADELPHIA																
SE	FORENSIC CHEM. CTR	(b)(2)&(b)(7)(E)															
	REGIONAL STAFF																
	ATLANTA																
	FLORIDA																
	NEW ORLEANS																
SW	SAN JUAN	(b)(2)&(b)(7)(E)															
	REGIONAL LAB																
	REGIONAL STAFF																
	DALLAS																
	DENVER																
PA	KANSAS CITY	(b)(2)&(b)(7)(E)															
	SOUTHWEST IMPORT DISTRICT																
	REGIONAL LAB																
	REGIONAL STAFF																
	LOS ANGELES																
	SAN FRANCISCO	(b)(2)&(b)(7)(E)															
	SEATTLE																
	PACIFIC REGIONAL LAB - SW																
	PACIFIC REGIONAL LAB - NW	(b)(2)&(b)(7)(E)															
HOURS PER OPERATION	150.0										200.0						
TOTAL HOURS	1500										400	475					
CONVERSION FACTOR	950										950	950					
TOTAL OPERATIONAL FTEs	1.58	0.42	0.50														

7. REMARKS

\* 42008 GMP Inspections,  
42008A Pre-License Inspections  
All inspections will be performed by Core Team Biologics. Field time is for district support to Team Biologics.  
No separate resources are planned for 42008A, use above resources as needed.  
Report accomplishments under appropriate operation code and PAC.

Field Investigation Hours may be used for any Core Team Program.

Personnel Types Required: Investigator, Core Team Biologics

1. PROGRAM/ASSIGNMENT TITLE IRBs, Sponsor/Monitor/Contract Research Organizations, Clinical Investigators (PDUFA Domestic & Foreign)	2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42
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3. PROGRAM/ASSIGNMENT CODE(S) 42809-IRB, 42810-Spon/Monitor/CROs, 42811 Clinical Investigator *	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 4.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S *	2 D O M E S T I C I N V E S T I G A T I O N S (Hours)	3 D O M E S T I C S A M P L E C O L L	4 I M P O R T S A M P L E C O L L	5 F I E L D E X A M S/ T E S T S	6 I M P O R T F I E L D E X A M S	7 D O M E S T I C T O B E	8 I M P O R T S A M P L E S T O B E A N A L Y Z E D	9 O T H E R O P E R A T I O N S (Hours)
	TOTAL FIELD		48							
NE	HEADQUARTERS	(b)(2)&								
	REGIONAL STAFF	(b)(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		79.2								
TOTAL HOURS		3802								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTES		4.00								

9. REMARKS

\* Resources for PACs 42809, 42810, and 42811 are planned under PAC 42811 Clinical Investigators. Use above resources for Foreign Inspections as needed. Inspections are to be conducted only when assignments are received from CBER. Report accomplishment hours under appropriate PAC. Report Foreign Inspections under Operation Code 11.

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers (Biologics)			2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42							
3. PROGRAM/ASSIGNMENT CODE(S) 42845A, B, C *			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 0.5		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD		11							
NE	HEADQUARTERS	(b)(2)&								
	REGIONAL STAFF	(b)(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
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	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		43.2								
TOTAL HOURS		475								
CONVERSION FACTOR		950								
TOTAL OPERATIONAL FTEs		0.50								

7. REMARKS

No Investigation Hours or Foreign Inspections are planned, use above resources as needed.

\* PACs changed from 42830C,L to 42845A,B,C in FY05  
 42845A Level 1 Inspections;  
 42845B Level 2 Inspections;  
 42845C Level 3 Inspections

Note: Inspections of Manufacturers of Blood Bank Software should be reported under this program.

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE Inspection of Plasma Derivatives of Human Origin				2. PPS PROJECT NAME/NUMBER Blood and Blood Products - 42						
3. PROGRAM/ASSIGNMENT CODE(S) 42848A, F, G; 41848A, F, G Domestic & Foreign *			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 3.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 DOMESTIC LICENSED INSPECT- IONS	1 FOREIGN LICENSED INSPECT- IONS	3 DOMESTIC SAMPLE COLL	2 DOMESTIC INVESTI- GATIONS (Hours)	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	5	8							
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		250.0	200.0							
TOTAL HOURS		1250	1600							
CONVERSION FACTOR		950	950							
OPERATIONAL FTEs		1.32	1.68							
7. REMARKS										
<p>* Core Team Compliance Program new in FY05 - Inspection of Biological Drug Products (CBER), (Previously covered by PAC 42006):                  All Inspections will be performed by Core Team Biologics.                  42848A Pre-Licensed Inspection - Plasma Derivatives, 42848F Level 1 CGMP Inspection - Plasma Derivative,                  42848G Level 2 CGMP Inspection - Plasma Derivatives; 41848A Pre-Licensed Inspection-Therapeutic Drugs,                  41848F Level 1 CGMP Inspection - Therapeutic Drugs, 41848G Level 2 CGMP Inspection - Therapeutic Drugs</p> <p>No separate resources are planned for Pre-License Inspections, or Therapeutic Drugs, use above resources as needed.                  All resources are planned under PAC 42848F.</p> <p>Report Foreign Inspections under Operation Code 11.                  Personnel Types Required: Core Team Biologics, Investigator</p>										



1. PROGRAM/ASSIGNMENT TITLE IRBs, Sponsor/Monitor/CROs, Clinical Investigators (PDUFA)			2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45							
3. PROGRAM/ASSIGNMENT CODE(S) 45809 IRBs, 45810 Spon/Mon/CROs, 45811 Clinical Investigators			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 7.0		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS *	2 INVESTI- GATIONS (HOURS)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	SPECIALIZED									
	TOTAL FIELD	83								
NE	HEADQUARTERS	(b)(2)&(b)								
	REGIONAL STAFF	(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT OPERATION									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
TOTAL	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	80.1								
	TOTAL HOURS	6648								
	CONVERSION FACTOR	950								
	TOTAL OPERATIONAL FTEs	7.00								

7. REMARKS

\* Resources for PACs 45809, 45810, and 45811 are planned under PAC 45811 Clinical Investigators. Use above resources for Foreign Inspections as needed. Inspections are to be conducted only when assignments are received from CBER. Report accomplishment hours under appropriate PAC. Report Foreign Inspections under Operation Code 11.

Personnel Types Required: Investigator

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Allergenic Products (Post-Market & Pre-License)				2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45						
3. PROGRAM/ASSIGNMENT CODE(S) 45848A,F,G Domestic/Foreign *			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 0.7			
R E G I O N	6.	1	1	2	3	4	6	7	8	9
	DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC- TIONS	FOREIGN INSPEC- TIONS	DOMESTIC INVESTI- GATIONS (HOURS)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	IMPORT FIELD EXAMS/ TESTS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	TOTAL FIELD	5	1							
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
PA	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		109.0	121.0							
TOTAL HOURS		545	121							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		0.57	0.13							

7. REMARKS

\* New in FY05 Core Team Compliance Program - Inspection of Biological Drug Products (CBER)  
 (Previously covered by PAC 45001):  
 PAC 45848A Pre-License Inspection - Allergenic  
 PAC 45848F Level 1 CGMP Inspection - Allergenic  
 PAC 45848G Level 2 CGMP Inspection - Allergenic  
 All Inspections will be conducted by Core Team Biologics.  
 Resources are planned under PAC 45848F. Use Resources As Needed and Report Under Appropriate PAC.

Personnel Types Required: Investigator, Core Team Biologics  
 Report Foreign Inspections under Operation Code 11.

1. PROGRAM/ASSIGNMENT TITLE Inspection of Licensed Vaccine Products (Post-Market)	2. PPS PROJECT NAME/NUMBER Vaccines and Allergenic Products - 45
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3. PROGRAM/ASSIGNMENT CODE(S) 45848B,C,D Domestic/Foreign * 45848H Off-Year Flu Vaccine	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 5.5
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R E G I O N	6	1	1	2	3	5	6	7	8	9
	DISTRICT/ SPECIALIZED LABORATORY	DOMESTIC INSPEC- TIONS	FOREIGN INSPEC- TIONS	DOMESTIC INVESTI- GATIONS (Hours)	DOMESTIC INVESTI- GATIONS (HOURS)	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS/ TESTS	DOMESTIC SAMPLES TO BE ANALYZED	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	TOTAL FIELD	10	11	501						
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		225.0	225.0							
TOTAL HOURS		2250	2475	501						
CONVERSION FACTOR		950	950	950						
TOTAL OPERATIONAL FTEs		2.37	2.61	0.53						

7. REMARKS  
 \* New Core Team Compliance Program in FY05 - Inspection of Biological Drug Products (CBER):  
 (Previously covered by PAC 45002)  
 45848B Pre-License Inspection - Vaccines;  
 45848C Level 1 CGMP Inspection - Vaccines;  
 45848D Level 2 CGMP Inspection - Vaccines.  
 45848H Off-Year Flu Vaccine: for inspecting the 50% of firm inventory not scheduled for inspection in this year  
 All inspections will be performed by Core Team Biologics.  
 Resources are planned under 45848C. Use Resources As Needed and Report Under Appropriate PAC.  
 Field Investigation Hours may be used to assist any Core Team Program.

Personnel Types Required: Investigator, Core Team Biologics  
 Report Foreign Inspections under Operation Code 11.

**CENTER FOR DRUG EVALUATION AND RESEARCH  
RESOURCE SUMMARY  
FY 2010**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs
		DOMESTIC	IMPORT	FOREIGN	
	<b>TOTAL</b>	219.6	33.9	86.5	340.0
46	NEW DRUG EVALUATION	10.5		14.0	24.5
48	BIORESEARCH MONITORING HUMAN DRUGS	45.7		19.5	65.2
52	GENERIC DRUG EVALUATION	5.0		10.0	15.0
53	POSTMARKETING SURVEILLANCE AND EPIDEMIOLOGY HUMAN DRUGS	10.0		1.0	11.0
56	DRUG QUALITY ASSURANCE	119.9	33.9	42.0	195.8
63	UNAPPROVED AND MISBRANDED DRUGS	9.5			9.5
88	INTERAGENCY COOPERATIVE ACTIVITIES	19.0			19.0



1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Investigations -Domestic (PDUFA)			2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46					
3. PROGRAM/ASSIGNMENT CODE(S) 46832, 46832B, 46832C 46R845			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 9.5		
R E G I O N	6.	1	1	3	7			
	DISTRICT/ SPECIALIZED LABORATORY	NDA# TO INSPECT	CHEMIST INSPECT (HOURS)	DOMESTIC SAMPLE COLL	DSA# PROFILE (Hours)			
	TOTAL FIELD	158	523	17	17			
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)						
	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
WEAC								
CE	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
FORENSIC CHEM. CTR								
SE	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	SAN JUAN							
REGIONAL LAB								
SW	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
	SOUTHWEST IMPORT DISTRICT							
REGIONAL LAB								
PA	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LAB - SW							
PACIFIC REGIONAL LAB - NW								
HOURS PER OPERATION		49.0		6.0	47.9			
TOTAL HOURS		7742	523	102	814			
CONVERSION FACTOR		950	950	950	1180			
TOTAL OPERATIONAL FTES		8.15	0.55	0.11	0.69			
7. REMARKS  *Includes Microbiologists on Inspections.								

1. PROGRAM/ASSIGNMENT TITLE NDA Pre-Approval Inspections/Investigations - Foreign (PDUFA)			2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46				
3. PROGRAM/ASSIGNMENT CODE(S) *46832, 46832B, 46832C, 46832D		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 13.0		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS ++	1 CHEMIST INSPS (Hours)  **			9 OTHER OPERATIONS (Hours)	
	TOTAL FIELD	130	3500				
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)					
	REGIONAL STAFF						
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB						
WEAC							
CE	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
	PHILADELPHIA						
FORENSIC CHEM. CTR							
SE	REGIONAL STAFF						
	ATLANTA						
	FLORIDA						
	NEW ORLEANS						
	SAN JUAN						
SW	REGIONAL LAB						
	REGIONAL STAFF						
	DALLAS						
	DENVER						
	KANSAS CITY						
PA	SOUTHWEST IMPORT DISTRICT						
	REGIONAL LAB						
	REGIONAL STAFF						
	LOS ANGELES						
	SAN FRANCISCO						
SEATTLE							
PACIFIC REGIONAL LAB - SW							
PACIFIC REGIONAL LAB - NW							
HOURS PER OPERATION		68.0					
TOTAL HOURS		8840	3500				
CONVERSION FACTOR		950	950				
TOTAL OPERATIONAL FTEs		9.31	3.68				
7 REMARKS <p>* Report as follows: Insp./Chem on Insp under foreign operation code 11, Pac Code 46832; M. Valid.-46832; Profile ISCs &amp; ISAs - 46832B; Biotest ISCs &amp; ISAs (not planned) if collected -46832C. ** Includes microbiologists on inspections.</p> <p>++ Use PAC 46832D to report work conducted under the President's Emergency Plan for AIDS Relief (PEPFAR).</p>							

1. PROGRAM/ASSIGNMENT TITLE Pre-Licensed Biotech (BLA) Inspections/Investigations Domestic and Foreign (PDUFA)			2. PPS PROJECT NAME/NUMBER New Drug Evaluation - 46				
3. PROGRAM/ASSIGNMENT CODE(S) 46832M		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 2.0		
R E G I O N	6	1	1				
	DISTRICT/ SPECIALIZED LABORATORY	INSPECT <i>Domestic</i>	INSPECT <i>Foreign</i>				
	TOTAL FIELD	19	14				
	HEADQUARTERS	(b)(2)&(b)(7)(E)					
NE	REGIONAL STAFF						
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB						
	WEAC						
CE	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
	PHILADELPHIA						
SE	FORENSIC CHEM. CTR						
	REGIONAL STAFF						
	ATLANTA						
	FLORIDA						
	NEW ORLEANS						
SW	SAN JUAN						
	REGIONAL LAB						
	REGIONAL STAFF						
	DALLAS						
	DENVER						
PA	KANSAS CITY						
	SOUTHWEST IMPORT DISTRICT						
	REGIONAL LAB						
	REGIONAL STAFF						
	LOS ANGELES						
	SAN FRANCISCO						
	SEATTLE						
	PACIFIC REGIONAL LAB - SW						
	PACIFIC REGIONAL LAB - NW						
	HOURS PER OPERATION	49.0	68.0				
	TOTAL HOURS	931	952				
	CONVERSION FACTOR	950	950				
	TOTAL OPERATIONAL FTES	0.98	1.00				
7. REMARKS  * Includes Microbiologists on Inspections.							



1. PROGRAM/ASSIGNMENT TITLE In Vivo Bioequivalence (Pre-Approval)			2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48				
3. PROGRAM/ASSIGNMENT CODE(S) 48001 (ANDAs) 48001A (NDAs) (PDUFA)			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 4.5	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 48001 ANDA INSP EC- TIONS  DOMESTIC	1 48001A NDA INSP EC- TIONS (PDUFA) DOMESTIC				
	TOTAL FIELD	24	29				
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)					
	REGIONAL STAFF						
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB						
WEAC							
CE	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
	PHILADELPHIA						
FORENSIC CHEM. CTR							
SE	REGIONAL STAFF						
	ATLANTA						
	FLORIDA						
	NEW ORLEANS						
	SAN JUAN						
REGIONAL LAB							
SW	REGIONAL STAFF						
	DALLAS						
	DENVER						
	KANSAS CITY						
	SOUTHWEST IMPORT DISTRICT						
REGIONAL LAB							
PA	REGIONAL STAFF						
	LOS ANGELES						
	SAN FRANCISCO						
	SEATTLE						
	PACIFIC REGIONAL LAB - SW						
PACIFIC REGIONAL LAB - NW							
HOURS PER OPERATION		74.0	85.0				
TOTAL HOURS		1776	2465				
CONVERSION FACTOR		950	950				
TOTAL OPERATIONAL FTEs		1.87	2.59				
7. REMARKS  Assignments issued by the Center will identify the PDUFA Pre-Approval High Priority Classification.  An estimate of percentage of time for each PAC is: Non-PDUFA 48001 (ANDA) 43%, PDUFA 48001A (NDA) 57%.          Personnel Types Required: Investigator							

1 PROGRAM/ASSIGNMENT TITLE Foreign Inspections (NDA - PDUFA) (ANDA - Pre-Approval)			2 PPS PROJECT NAME/NUMBER Bioresearch Monitoring: Human Drugs - 48						
3 PROGRAM/ASSIGNMENT CODE(S) 48001,A; 48808; 48001D,E, 48811D NDA &, ANDA *			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5 OPERATIONAL FTE POSITIONS 3.5		
REGION	DISTRICT/ SPECIALIZED LABORATORY	1 FOREIGN 48001A NDA INSPEC- TIONS (PDUFA)	1 FOREIGN 48001 ANDA INSPEC- TIONS (PRE-APPR)	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	7 DOMESTIC SAMPLES TO BE ANALYZED	8 IMPORT SAMPLES TO BE ANALYZED	9	
	TOTAL FIELD	23	18						
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
SE	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
SW	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
PA	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
HOURS PER OPERATION		78.0	85.0						
TOTAL HOURS		1794	1530						
CONVERSION FACTOR		950	950						
TOTAL OPERATIONAL FTEs		1.89	1.61						

7 REMARKS

\* Planned inspections include: 48001,A In Vivo Bioequivalence, 48808 GLPs (PDUFA), PACs 48001D PEPFAR NDA Bioequivalence, 48001E PEPFAR ANDA Bioequivalence, and 48811D PEPFAR Clinical Investigations .

Report Inspections under Appropriate PAC, Foreign Inspections under Operation Code 11.  
HIGH PRIORITY for NDA inspections.  
48001D PEPFAR NDA Bioequivalence; 48001E PEPFAR ANDA Bioequivalence; 48811D PEPFAR Clinical Investigations.  
NDA PEPFAR Resources are planned under 48001A and ANDA PEPFAR Resources are planned under 48001.  
We are not planning separate PEPFAR work.

Inspections of bioequivalence manufacturers and clinical studies submitted in NDAs and ANDAs.  
Data audit under PEPFAR will be verified by on site inspections.

Personnel Types Required: Investigator, National Expert

1. PROGRAM/ASSIGNMENT TITLE Good Laboratory Practices; Institutional Review Board; Sponsors, Contract Research Org., Monitors; Clinical Investigators (PDUFA)		2. PPS PROJECT NAME/NUMBER Bioresearch Monitoring; Human Drugs - 48	
3. PROGRAM/ASSIGNMENT CODE(S) 48808, 48809, 48809A, 48810		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 13.1

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	1	1				
		GLP INSP CTIONS 48808	NATL EXPERT INVEST- GATIONS (Hours) 48808 - GLP	IRB INSPECTIONS 48809, 48809A §	SPONSOR, CRO, MONITORS INSPECTIONS 48810 **				
	<b>TOTAL FIELD</b>	17	318	106	45				
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF	(b)(2)&(b)(7)(E)							
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM CTR								
	REGIONAL STAFF								
SE	ATLANTA	(b)(2)&(b)(7)(E)							
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF	(b)(2)&(b)(7)(E)							
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
PA	REGIONAL LAB	(b)(2)&(b)(7)(E)							
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LAB - SW	(b)(2)&(b)(7)(E)							
	PACIFIC REGIONAL LAB - NW								
	HOURS PER OPERATION	92.8		81.0	90.0				
	TOTAL HOURS	1578	318	6486	4050				
	CONVERSION FACTOR	950	950	950	950				
	TOTAL OPERATIONAL FTEs	1.66	0.33	6.81	4.26				

9. REMARKS  
 48808:  
 Resources planned for Inspections may also be used for DSCs.  
 Planned Inspections include Surveillance Inspections and any Assignments from CDER to cover studies identified by CDER. CDER assignments, i.e. Directed Inspections, cover studies associated with IND's and NDA's.  
 Resources for Good Laboratory Practice (GLP) Foreign Inspections are planned under 48001A (see page 48-3).  
 \* Institutional Review Board  
 \*\* Sponsors, Contract Research Organizations, and Monitors  
 §- 48809A: Resource (1 FTE) for the Radioactive Drug Research Committee (RDRC) is not planned separately. However, please use above resources as needed and report RDRC work under PAC 48809A.  
 Personnel Types Required: Investigator, National Expert





<b>1 PROGRAM/ASSIGNMENT TITLE</b> ANDA Pre - Approval Inspections/Inv. - Domestic				<b>2. PPS PROJECT NAME/NUMBER</b> Generic Drug Evaluation - 52					
<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 52832, B, C		<b>4 WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			<b>5 OPERATIONAL FTE POSITIONS</b> 5.0				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 ANDAs TO INSPECT		3 DOMESTIC SAMPLE COLL		7 DOMESTIC SAMPLE ANALYSES PROFILE (Hours)	7 BIOTEST (Chem)		
	<b>TOTAL FIELD</b>	<b>50</b>		<b>41</b>		<b>31</b>	<b>31</b>		
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)			
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
WEAC									
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
REGIONAL LAB									
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
REGIONAL LAB									
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LAB - SW								
PACIFIC REGIONAL LAB - NW									
<b>HOURS PER OPERATION</b>		49.5		7.6		50.0	30.0		
<b>TOTAL HOURS</b>		2475		312		1550	930		
<b>CONVERSION FACTOR</b>		950		950		1180	1180		
<b>TOTAL OPERATIONAL FTEs</b>		2.81		0.33		1.31	0.79		

7. REMARKS

ANDA Pre - Approval Inspections/Investigations - Foreign					2. PPS PROJECT NAME/NUMBER Generic Drug Evaluation - 52				
3. PROGRAM/ASSIGNMENT CODE(S) 52832, 52832B, 52832C, 52832E			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 10.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS * (Foreign) ++	1 CHEMIST INSP. (Hours) (Foreign) **	1 INVEST. HRS		5 IMPORT SAMPLE COLL ***	8 IMPORT SAMPLE ANALYSES (Chem) ****	8 IMPORT SAMPLE ANALYSES BIOTEST (Chem) ****	
	TOTAL FIELD	44	1900	218		203	101	102	
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)				(b)(2)&(b)(7)(E)			
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	Southwest Import District								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
SEATTLE									
PACIFIC REGIONAL LAB - SW									
PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION		70.9				3.0	30.0	15.0	
TOTAL HOURS		3120	1900	218		609	3030	1530	
CONVERSION FACTOR		950	950	950		950	1180	1180	
TOTAL OPERATIONAL FTEs		3.28	2.00	0.23		0.64	2.57	1.30	

7. REMARKS

\* Report as follow: Insp./Chem on Insp. under foreign operation code 11 Pac Code 52832;

++ PEPFAR inspections included in total. Use PAC 52832E to report work conducted under the President's Emergency Plan for AIDS Relief (PEPFAR).

Profile ISCs & ISAs -52832B; Biotest ISCs &ISAs under PAC 52832C.

\*\* Includes microbiologists on inspections \*\*\* Samples are collected at foreign manufacturers.

\*\*\*\* NRL analyzes all Profile/Biotest ISCs and methods development ISAs.



1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Adverse Drug Experience Reporting Regulations		2. PPS PROJECT NAME/NUMBER Postmarketing Surveillance and Epidemiology: Human Drugs - 53								
3. PROGRAM/ASSIGNMENT CODE(S) 53001A, 53001B *			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 9.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS DOMESTIC	1 INSPEC- TIONS FOREIGN						9 MISC. HOURS	
	TOTAL FIELD	115	15							
N E	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
C E	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
S E	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	REGIONAL LAB									
S W	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
P A	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
PACIFIC REGIONAL LAB - NW										
PACIFIC REGIONAL LAB - SW										
HOURS PER OPERATION		66.0	64.9							
TOTAL HOURS		7590	974							
CONVERSION FACTOR		950	950							
TOTAL OPERATIONAL FTEs		7.99	1.03							

7. REMARKS  
\*Report both Domestic and Foreign inspections under 53001A for Center-Initiated and 53001B for District-Initiated.





Drug Process Inspections - Domestic	2 PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3 PROGRAM ASSIGNMENT CODE(S) 56002, A, B, C, D, F 56832, 56R359	4 WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5 OPERATIONAL FTE POSITIONS 69.4
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R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS	1 INVESTI- GATIONS (Hours)	1 CHEMIST ON INSPECTIONS (Hours)	1 MICRO ON INSPEC- TIONS (Hours)	3 DOMESTIC SAMPLE COLL **	3 DOMESTIC SAMPLE COLL (CHEM)	3 DOMESTIC SAMPLE COLL (MICRO)	7 DOMESTIC SAMPLES TO BE ANALYZED (CHEM)	7 DOMESTIC SAMPLES TO BE ANALYZED (MICRO)
	TOTAL FIELD	926	950	2461	1968	350	229	40	229	40
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	55.0				5.0			38.0	28.0
	TOTAL HOURS	50930	950	2461	1968	1750			8702	1120
	CONVERSION FACTOR	950	950	950	950	950			1180	1180
	TOTAL OPERATIONAL FTEs	53.61	1.00	2.59	2.07	1.84			7.37	0.95

7. REMARKS

\* Hours for certification audits or general investigations as needed by the District. Report Certification Audit hrs under 56R359

\*\* DSCs not analyzed are doc. samples.

*Domestic Sample Collections (Chem and Micro): These areas break out the sample collections and are only guidelines for Districts.*

1. PROGRAM/ASSIGNMENT TITLE Foreign Drug Inspections	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56002,A,B,C,D,F 56832, 56R359	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 40.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS FOREIGN *	1 CHEMIST INSPEC- TIONS (Hours) FOREIGN **						
	<b>TOTAL FIELD</b>	<b>473</b>	<b>11153</b>						
	HEADQUARTERS	(b)(2)&(b)(7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LAB - SW								
	PACIFIC REGIONAL LAB - NW								
	HOURS PER OPERATION	56.7							
	TOTAL HOURS	26819	11153						
	CONVERSION FACTOR	950	950						
	TOTAL OPERATIONAL FTEs	28.23	11.74						

7. REMARKS

\* Foreign inspections (DPI) are planned under 56002 and should be reported under operation 11 PACs 56002A, B, C, D, F, 56832.

\*\* Time planned in this column may be used by chemists or microbiologists.

1. PROGRAM/ASSIGNMENT TITLE DRUG Process Inspections- Domestic (Gas Manufacturer)			2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56						
3. PROGRAM/ASSIGNMENT CODE(S) 56002E			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 6.0		
R E G I O N	6	1	2	3	4	5	7	8	9
	DISTRICT/ SPECIALIZED LABORATORY	PLANNED INSPECTIONS  MEDICAL GAS	INVESTI- GATION Hours	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	DOMESTIC SAMPLE ANALYSES	IMPORT SAMPLES ANALYSES	MISC. HOURS
	TOTAL FIELD	190							
	HEADQUARTERS	(b)(2)&(b)(7) (E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
FORENSIC CHEM. CTR									
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
HOURS PER OPERATION		30.0							
TOTAL HOURS		5700							
CONVERSION FACTOR		950							
TOTAL OPERATIONAL FTEs		6.00							
9. REMARKS * Total number of planned gas inspections in the Program for FY 2010.									

Drug Process Inspections - Biotech Manufacturers Domestic		2 PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56					
3 PROGRAM/ASSIGNMENT CODE(S) 56002M		4 WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5 OPERATIONAL FTE POSITIONS 4.0		
R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS					
	TOTAL FIELD	69					
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)					
	REGIONAL STAFF						
	NEW ENGLAND						
	NEW YORK						
	REGIONAL LAB						
CE	WEAC						
	REGIONAL STAFF						
	BALTIMORE						
	CHICAGO						
	CINCINNATI						
	DETROIT						
	MINNEAPOLIS						
	NEW JERSEY						
SE	PHILADELPHIA						
	FORENSIC CHEM. CTR						
	REGIONAL STAFF						
	ATLANTA						
	FLORIDA						
SW	NEW ORLEANS						
	SAN JUAN						
	REGIONAL LAB						
	REGIONAL STAFF						
	DALLAS						
PA	DENVER						
	KANSAS CITY						
	SOUTHWEST IMPORT DISTRICT						
	REGIONAL LAB						
	REGIONAL STAFF						
	LOS ANGELES						
PA	SAN FRANCISCO						
	SEATTLE						
	PACIFIC REGIONAL LAB - SW						
	PACIFIC REGIONAL LAB - NW						
HOURS PER OPERATION		55.0					
TOTAL HOURS		3795					
CONVERSION FACTOR		950					
TOTAL OPERATIONAL FTEs		3.99					
7 REMARKS							

1 PROGRAM/ASSIGNMENT TITLE Drug Product Surveillance - Domestic Drugs			2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56							
3 PROGRAM/ASSIGNMENT CODE(S) 56008A			4 WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER					5. OPERATIONAL FTE POSITIONS 17.0 (4.3)		
R E G I O N	6	2	3	DOMESTIC SAMPLE COLL (CHEM)	DOMESTIC SAMPLE COLL (MICRO)	3 DOMESTIC IMPORT SAMPLE COLL NEW	DOMESTIC IMPORT SAMPLE COLL (CHEM)	DOMESTIC IMPORT SAMPLE COLL (MICRO)	7 DOMESTIC SAMPLES ANALYZED (CHEM)	7 DOMESTIC SAMPLES ANALYZED (MICRO)
	DISTRICT/ SPECIALIZED LABORATORY	INVESTIGATIONS (Hours)	DOMESTIC SAMPLE COLL							
	TOTAL FIELD	700	40	30	10	380	320	60	30	10
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
PA	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION			5.5			5.5			37.5	22.0
TOTAL HOURS		700	220			2080			1125	220
CONVERSION FACTOR		950	950			950			1180	1180
TOTAL OPERATIONAL FTEs		0.74	0.23			2.20			0.95	0.19
9 REMARKS										
<p><b>NEW</b> Reporting Guidance: Report domestic-import sample collections and sample analyses under 56008A.</p> <p>Domestic Sample Collections (Chem and Micro): These areas break out the sample collections and are only guidelines for Districts.</p>										

FY 2010 ORA Workplan

October 1, 2009

1 PROGRAM/ASSIGNMENT TITLE Drug Product Surveillance - Domestic Drugs			2 PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56							
3 PROGRAM/ASSIGNMENT CODE(S) 56008A			4 WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5 OPERATIONAL FTE POSITIONS 17.0 (12.7)			
R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	7 DOMESTIC IMPORT SAMPLES ANALYZED (CHEM)	7 DOMESTIC IMPORT SAMPLES ANALYZED (MICRO)		7 METHODS DEVELOPMENT HOURS (Chem)					
	TOTAL FIELD	320	60		1660					
N E	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
C E	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	FORENSIC CHEM. CTR									
S E	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	REGIONAL LAB									
S W	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	REGIONAL LAB									
P A	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	REGIONAL LAB - NW									
HOURS PER OPERATION		37.5	22.0							
TOTAL HOURS		12000	1320		1660					
CONVERSION FACTOR		1180	1180		1180					
TOTAL OPERATIONAL FTEs		10.17	1.12		1.41					
9 REMARKS										

1. PROGRAM/ASSIGNMENT TITLE Drug Product Surveillance - Imported Drugs				2. PPS PROJECT NAME/NUMBER Drug Quality Assurance-56				
3. PROGRAM/ASSIGNMENT CODE(S) 56008H, 56R833, 56R824, 99R833			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER		5. OPERATIONAL FTE POSITIONS 33.9			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	2 IMPORT ENTRY REVIEW HOURS	2 IMPORT INVESTIGATIONS HOURS --	IMPORT FIELD EXAMS	MAIL/ COURIERS REVIEWS INV HOURS	4 IMPORT SAMPLE COLLECT- IONS	8 IMPORT SAMPLES ANALYZED APIs  CHEM	8 IMPORT SAMPLES ANALYZED FINISHED DOSAGE CHEM
	TOTAL FIELD		10992	3296	6200	8341	202	101
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)						
	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
CE	WEAC							
	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
SE	FORENSIC CHEM. CTR							
	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
SW	SAN JUAN							
	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
	DENVER							
PA	KANSAS CITY							
	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
PA	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LAB - SW							
	PACIFIC REGIONAL LAB - NW							
HOURS PER OPERATION				1.0		2.7	38.0	25.0
TOTAL HOURS		10992	3296	6200	8341	545	3838	2525
CONVERSION FACTOR		1200	950	950	950	950	1180	1180
TOTAL OPERATIONAL FTEs		9.16	3.47	6.53	8.78	0.57	3.25	2.14
7 REMARKS								
<p><u>Reporting Guidance:</u></p> <ul style="list-style-type: none"> <li>- Import Entry Reviews (electronic and manual-- operation code 14) PAC 56R833;</li> <li>- Filer Evaluations (operation code 95) PAC 99R833;</li> <li>- Follow-Up to Refusals 56R824, 63R824</li> <li>- Import Label Reviews, Import Field Exams under PACs 56008H, 56014/A, 63001, 63002;</li> <li>- Report finished dosage form drugs and APIs collected at the site of entry under 56008H.</li> </ul> <p>** Import investigation hours are for filer evaluations, follow-up to refusals, label exams, and other operations as required by the District to cover program priorities. Districts should report time under the appropriate operation and PAC for the activities performed.</p> <p>Use CT PAC 56R845 only when specific CT work is performed.</p>								

1. PROGRAM/ASSIGNMENT TITLE Drug Quality Reporting System (DQRS)/ NDA-Field Alert Reporting				2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56				
3. PROGRAM/ASSIGNMENT CODE(S) 56021A, 56021B			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 4.5	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSP EC T I O N S	2 INVEST I G A T I O N S (Hours)	3 D O M E S T I C S A M P L E C O L L			7 D O M E S T I C S A M P L E S T O B E A N A L Y Z E D (Chem)	
	TOTAL FIELD	126		33			33	
NE	HEADQUARTERS	(b)(2)&(b)		(b)(2)&(b)			(b)(2)&(b)	
	REGIONAL STAFF	(7)(E)		(7)(E)			(7)(E)	
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
CE	WEAC							
	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
FORENSIC CHEM. CTR								
SE	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	SAN JUAN							
SW	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
PA	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LAB - SW							
	PACIFIC REGIONAL LAB - NW							
HOURS PER OPERATION		25.0		5.2			35.0	
TOTAL HOURS		3150		172			1155	
CONVERSION FACTOR		950		950			1180	
TOTAL OPERATIONAL FTEs		3.32		0.18			0.98	
7. REMARKS								

FY 2010 ORA Workplan

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1. PROGRAM/ASSIGNMENT TITLE Enforcement of the Prescription Drug Marketing Act (PDMA)				2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56			
3. PROGRAM/ASSIGNMENT CODE(S) 56022, 56022A			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 2.0	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1. INSPEC- TIONS	2. INVESTI- GATIONS (Hours)	3. DOMESTIC SAMPLE COLL		7. DOMESTIC SAMPLES TO BE ANALYZED (Chem)	
	TOTAL FIELD	43	294	34		34	
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)					
	REGIONAL STAFF	(b)(2)&(b)(7)(E)					
	NEW ENGLAND	(b)(2)&(b)(7)(E)					
	NEW YORK	(b)(2)&(b)(7)(E)					
	REGIONAL LAB WEAC	(b)(2)&(b)(7)(E)					
CE	REGIONAL STAFF	(b)(2)&(b)(7)(E)					
	BALTIMORE	(b)(2)&(b)(7)(E)					
	CHICAGO	(b)(2)&(b)(7)(E)					
	CINCINNATI	(b)(2)&(b)(7)(E)					
	DETROIT	(b)(2)&(b)(7)(E)					
	MINNEAPOLIS	(b)(2)&(b)(7)(E)					
	NEW JERSEY	(b)(2)&(b)(7)(E)					
	PHILADELPHIA FORENSIC CHEM CTR	(b)(2)&(b)(7)(E)					
SE	REGIONAL STAFF	(b)(2)&(b)(7)(E)					
	ATLANTA	(b)(2)&(b)(7)(E)					
	FLORIDA	(b)(2)&(b)(7)(E)					
	NEW ORLEANS	(b)(2)&(b)(7)(E)					
	SAN JUAN REGIONAL LAB	(b)(2)&(b)(7)(E)					
SW	REGIONAL STAFF	(b)(2)&(b)(7)(E)					
	DALLAS	(b)(2)&(b)(7)(E)					
	DENVER	(b)(2)&(b)(7)(E)					
	KANSAS CITY	(b)(2)&(b)(7)(E)					
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB	(b)(2)&(b)(7)(E)					
PA	REGIONAL STAFF	(b)(2)&(b)(7)(E)					
	LOS ANGELES	(b)(2)&(b)(7)(E)					
	SAN FRANCISCO	(b)(2)&(b)(7)(E)					
	SEATTLE	(b)(2)&(b)(7)(E)					
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW	(b)(2)&(b)(7)(E)					
HOURS PER OPERATION		30.0		2.0		11.0	
TOTAL HOURS		1290	294	68		374	
CONVERSION FACTOR		950	950	950		1180	
TOTAL OPERATIONAL FTEs		1.38	0.31	0.07		0.32	
7. REMARKS							

1 PROGRAM/ASSIGNMENT TITLE Post-Approval Inspections/Investigations - Domestic			2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56						
3 PROGRAM/ASSIGNMENT CODE(S) 56843			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5 OPERATIONAL FTE POSITIONS 2.0		
R E G I O N	6.	1	2					8	
	DISTRICT/ SPECIALIZED LABORATORY	PLANNED INSPECTIONS	INVESTI- GATION Hours					MISC. HOURS	
	TOTAL FIELD	48							
NE	HEADQUARTERS	(b)(2)&(b)(7) (E)							
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
SE	PHILADELPHIA								
	FORENSIC CHEM CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
SW	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
PA	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL-SW								
	PACIFIC REGIONAL-NW								
HOURS PER OPERATION		40.0							
TOTAL HOURS		1920							
CONVERSION FACTOR		950							
TOTAL OPERATIONAL FTEs		2.02							
9. REMARKS									

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Post-Approval Inspections/Investigations - Foreign			<b>2. PPS PROJECT NAME/NUMBER</b> Drug Quality Assurance - 56					
<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 56843		<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			<b>5. OPERATIONAL FTE POSITIONS</b> 2.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 PLANNED INSPECTIONS	2 INVESTI- GATION Hours					3 MISC. HOURS
	<b>TOTAL FIELD</b>	<b>48</b>						
	HEADQUARTERS	(b)(2)&(b)(7) (E)						
NE	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
	WEAC							
CE	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
	FORENSIC CHEM. CTR							
SE	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	SAN JUAN							
	REGIONAL LAB							
SW	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
PA	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL-SW							
	PACIFIC REGIONAL-NW							
<b>HOURS PER OPERATION</b>		<b>40.0</b>						
<b>TOTAL HOURS</b>		<b>1920</b>						
<b>CONVERSION FACTOR</b>		<b>950</b>						
<b>TOTAL OPERATIONAL FTEs</b>		<b>2.02</b>						
<b>9. REMARKS</b>								

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Pharmacy Compounding				<b>2. PPS PROJECT NAME/NUMBER</b> Drug Quality Assurance - 56				
<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 56D015			<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			<b>5. OPERATIONAL FTE POSITIONS</b> 5.0		
R E G I O N	<b>6</b> DISTRICT/ SPECIALIZED LABORATORY	<b>1</b> INSP EC TIONS					<b>9</b> Misc. (Hours)	
	<b>TOTAL FIELD</b>	71						
NE	HEADQUARTERS	(b)(2)& (b)(7)(E)						
	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
CE	WEAC							
	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
SE	PHILADELPHIA							
	FORENSIC CHEM. CTR							
	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
SW	NEW ORLEANS							
	SAN JUAN							
	REGIONAL LAB							
	REGIONAL STAFF							
PA	DALLAS							
	DENVER							
	KANSAS CITY							
	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
PA	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LAB - SW							
	PACIFIC REGIONAL LAB - NW							
		67.4						
		4785						
		950						
		5.04						
<b>7. REMARKS</b>  Resources for collection and analysis of any samples under this program should be taken from Drug Product Surveillance - Domestic Drugs (56008A,C).								

1. PROGRAM/ASSIGNMENT TITLE Forensic Evaluation and Sample Analysis	2. PPS PROJECT NAME/NUMBER Drug Quality Assurance - 56
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3. PROGRAM/ASSIGNMENT CODE(S) 56R838, 56R831	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 10.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC CHEM (Hours) FORENSIC EVALUATION								
	<b>TOTAL FIELD</b>	<b>12050</b>								
NE	HEADQUARTERS	(b)(2)&(b)								
	REGIONAL STAFF	(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW PACIFIC REGIONAL LAB - NW									
HOURS PER OPERATION										
TOTAL HOURS		12050								
CONVERSION FACTOR		1205								
TOTAL OPERATIONAL FTEs		10.00								

7. REMARKS

The hours planned above are estimates. Report Forensic activities under the appropriate PAC 56R838; PODS operation code 03, Petition Evaluation, Methods Development or Forensic Evaluation; PODS operation 41 or 43 domestic or import sample analysis, PAC 56R838 or OCI PAC 56R831.



1. PROGRAM/ASSIGNMENT TITLE Internet, Health Fraud, & OTC Monographs				2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs - 63						
3. PROGRAM/ASSIGNMENT CODE(S) 63001A, 63D012			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 4.5				
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL.			7 DOMESTIC SAMPLES TO BE ANALYZED Chem			
	<b>TOTAL FIELD</b>	95	950	118			59			
	HEADQUARTERS	(b)(2)&(b)(7)(E)					(b)(2)&(b)(7)(E)			
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB - SW									
	PACIFIC REGIONAL LAB - NW									
	HOURS PER OPERATION	20.0		4.0			20.0			
	TOTAL HOURS	1900	950	472			1180			
	CONVERSION FACTOR	950	950	950			1180			
	TOTAL OPERATIONAL FTEs	2.00	1.00	0.50			1.00			
7. REMARKS										
*Not all samples collected will require analysis; some will be collected for documentary and label review.  Report Health Fraud and OTC Monograph work to PAC 63001A. Report Internet Drugs work to PAC 63D012.										

1. PROGRAM/ASSIGNMENT TITLE New Drugs (Prescription) Without Approved NDAs			2. PPS PROJECT NAME/NUMBER Unapproved and Misbranded Drugs - 63					
3. PROGRAM/ASSIGNMENT CODE(S) 63002			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 5.0		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVEST- GATIONS (Hours)					
	TOTAL FIELD	107	475					
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)						
	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
CE	WEAC							
	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
SE	PHILADELPHIA							
	FORENSIC CHEM. CTR							
	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
SW	NEW ORLEANS							
	SAN JUAN							
	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
PA	DENVER							
	KANSAS CITY							
	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
PA	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LAB - SW							
	PACIFIC REGIONAL LAB - NW							
HOURS PER OPERATION		40.0						
TOTAL HOURS		4280	475					
CONVERSION FACTOR		950	950					
TOTAL OPERATIONAL FTEs		4.51	0.50					
7. REMARKS  Report work under New Drugs (Rx) without Approved NDAs (formerly PAC 52002) to PAC 63002.								



1. PROGRAM/ASSIGNMENT TITLE Shelf Life Extension Projects	2. PPS PROJECT NAME/NUMBER Interagency Cooperative Activities - 88
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3. PROGRAM/ASSIGNMENT CODE(S) All Appropriate PACs	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 12.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS	2 INVESTI- GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	4 IMPORT SAMPLE COLL	5 FIELD EXAMS/ TESTS	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED (Chem) Hours	8 IMPORT SAMPLES TO BE ANALYZED	9 OTHER OPERATIONS (Hours)
	<b>TOTAL FIELD</b>							14160		
NE	HEADQUARTERS							(b)(2)&(b) (7)(E)		
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
CE	WEAC									
	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
SE	PHILADELPHIA									
	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	DALLAS									
	DENVER									
	KANSAS									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
PA	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LAB-SW									
	PACIFIC REGIONAL LAB-NW									
HOURS PER OPERATION										
TOTAL HOURS								14160		
CONVERSION FACTOR								1180		
TOTAL OPERATIONAL FTEs								12.00		

7. REMARKS  
 Five FTEs are assigned to this Program using dollars reimbursed by DOD.  
 Seven additional FTEs are assigned to this Program using dollars reimbursed by the Department of Homeland Security.

FY 2010 ORA Workplan

October 1, 2009

1. PROGRAM/ASSIGNMENT TITLE USP Reference Standards					2. PPS PROJECT NAME/NUMBER Interagency Cooperative Activities - 88					
3. PROGRAM/ASSIGNMENT CODE(S) 88R451			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 7.0			
R E G I O N	6	1	2	3	4	5	6	7	8	9
	DISTRICT/ SPECIALIZED LABORATORY	INSPEC- TIONS	INVESTI- GATIONS (Hours)	DOMESTIC SAMPLE COLL	IMPORT SAMPLE COLL	FIELD EXAMS/ TESTS	IMPORT FIELD EXAMS	DOMESTIC CHEM HOURS	IMPORT SAMPLES TO BE ANALYZED	OTHER OPERATIONS (Hours)
	TOTAL FIELD							8260		
NE	HEADQUARTERS							(b)(2)& (b)(7)(E)		
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LAB-SW										
PACIFIC REGIONAL LAB-NW										
HOURS PER OPERATION										
TOTAL HOURS								8260		
CONVERSION FACTOR								1180		
TOTAL OPERATIONAL FTEs								7.00		
7 REMARKS Seven FTEs are assigned to this Program using dollars reimbursed by United States Pharmacopeia.										

**CENTER FOR VETERINARY MEDICINE  
RESOURCE SUMMARY  
FY 2010**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTES
		DOMESTIC	IMPORT	FOREIGN	
	<b>TOTAL</b>	<b>101.3</b>	<b>16.3</b>	<b>5.5</b>	<b>123.1</b>
68	PRE-APPROVAL EVALUATION OF ANIMAL DRUGS AND FOOD ADDITIVES	4.9		3.5	8.4
71	MONITORING OF MARKETED ANIMAL DRUGS, FEEDS AND DEVICES	96.4	16.3	2.0	114.7



1. PROGRAM/ASSIGNMENT TITLE NADA Pre-Approval Inspections				2. PPS PROJECT NAME/NUMBER Pre-Approval Evaluation of Animal Drugs and Food Additives - 68				
3. PROGRAM/ASSIGNMENT CODE(S) 68001, 68001G			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 4.0		
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS *	1 CHEMIST ON INSP **	1 INSPEC- TIONS (Foreign) ***				
	<b>TOTAL FIELD</b>	<b>5</b>	<b>285</b>	<b>37</b>				
	HEADQUARTERS	(b)(2)&(b)(7)(E)						
NE	REGIONAL STAFF							
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
	WEAC							
CE	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
FORENSIC CHEM. CTR								
SE	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
	SAN JUAN							
SW	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
PA	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
SEATTLE								
PACIFIC REGIONAL LABORATORY-SW								
PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION		40.0		90.0				
TOTAL HOURS		200	285	3330				
CONVERSION FACTOR		950	950	950				
TOTAL OPERATIONAL FTEs		0.21	0.30	3.51				
7. REMARKS * New PAC; Resources for the Generic Animal Drug Pre-Approval Inspections PAC (68001G) are planned under 68001. ** Analyst will participate on inspections as necessary.  Districts and Laboratories should collect and analyze samples as needed by the program, time for these operations is planned under inspections and chemist on inspections.  *** Foreign inspections spread by DFI. Use Operation Code 11 to report foreign Inspections.   Workload Source: FACTS database (registered firms in IND 56, 67, and 68; Workload Obligation is "Yes" and Status is "Operational".)								





1. PROGRAM/ASSIGNMENT TITLE Animal Drug Manufacturing Inspections / Type A Medicated Articles		2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71															
3. PROGRAM/ASSIGNMENT CODE(S) 71001 /A /B, 71005 /A		<input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 12.3											
R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	1 INSP CTIONS	1 CHEM ON INSP (Hours)	1 INSP CTIONS (Foreign)	2 INVESTI GATIONS (Hours)	3 DOMESTIC SAMPLE COLL	DOMESTIC SAMPLE COLL (Chem)	6 IMPORT FIELD EXAMS	7 DOMESTIC SAMPLES TO BE ANALYZED (Chem)								
	TOTAL FIELD	205	475	25	250	50	20	100	20								
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)															
	REGIONAL STAFF																
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
WEAC																	
CE	REGIONAL STAFF																
	BALTIMORE																
	CHICAGO																
	CINCINNATI																
	DETROIT																
	MINNEAPOLIS																
	NEW JERSEY																
	PHILADELPHIA																
	FORENSIC CHEM CTR																
SE	REGIONAL STAFF																
	ATLANTA																
	FLORIDA																
	NEW ORLEANS																
	SAN JUAN																
SW	REGIONAL LAB																
	REGIONAL STAFF																
	DALLAS																
	DENVER																
	KANSAS CITY																
PA	SOUTHWEST IMPORT DISTRICT																
	REGIONAL LAB																
	REGIONAL STAFF																
	LOS ANGELES																
	SAN FRANCISCO																
	SEATTLE																
	PACIFIC REGIONAL LABORATORY-SW																
	PACIFIC REGIONAL LABORATORY-NW																
HOURS PER OPERATION										42.0		63.5		7.0		0.8	20.0
TOTAL HOURS										8610	475	1588	250	350		80	400
CONVERSION FACTOR										950	950	950	950	950		950	1180
TOTAL OPERATIONAL FTEs										9.06	0.50	1.67	0.26	0.37		0.08	0.34
9. REMARKS																	
<p>Inspections include product defects and adverse drug reaction follow up. Samples not analyzed are documentary samples. Investigational or official samples should be collected as appropriate.</p> <p>Resources for Type A Medicated Articles Program (71005/A) are now under 71001.</p> <p> The shaded area serves as a guideline for Districts on the specific types of samples that should be collected in order to match samples sent to the laboratories for analysis.</p> <p><u>Workload Source:</u> Resource distribution is based on the CVM risk model for ranking firms in this program.</p> <p>Foreign Inspections spread by Division of Field Investigations, DFI.</p>																	

1 PROGRAM ASSIGNMENT TITLE Feed Contaminants - DOMESTIC		2 PFS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71													
3 PROGRAM ASSIGNMENT CODE(S) 71003 A-K		4 WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER										5 OPERATIONAL FTE POSITIONS TOTAL 19.4 DOMESTIC 15.4 IMPORT 4.0			
R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	7 INSPEC- TIONS (Dioxin)	8 DOMESTIC SAMPLE COLL	9 DOMESTIC SAMPLE COLL Metals	10 DOMESTIC SAMPLE COLL Mycos	11 DOMESTIC SAMPLE COLL Micro	12 DOMESTIC SAMPLE COLL Chem	13 DOMESTIC SAMPLE COLL Diets	14 DOMESTIC SAMPLE COLL Antibiotics	15 DOMESTIC SAMPLE ANALYSIS Metals	16 DOMESTIC SAMPLE ANALYSIS Mycos	17 DOMESTIC SAMPLE ANALYSIS Micro	18 DOMESTIC SAMPLE ANALYSIS Chem	19 DOMESTIC SAMPLE ANALYSIS Diets	20 DOMESTIC SAMPLE ANALYSIS Antibiotics
HEADQUARTERS		(b)(2)&(b)(7)(E)													
NE	REGIONAL STAFF														
	NEW ENGLAND														
	NEW YORK														
	REGIONAL LAB														
CE	WEAC														
	REGIONAL STAFF														
	BALTIMORE														
	CHICAGO														
	CINCINNATI														
	DETROIT														
	MINNEAPOLIS														
	PHILADELPHIA														
SE	FORENSIC CHEM. CTR														
	REGIONAL STAFF														
	ATLANTA														
	FLORIDA														
SW	NEW ORLEANS														
	SAN JUAN														
	REGIONAL LAB														
	REGIONAL STAFF														
	DALLAS														
PA	DENVER														
	KANSAS CITY														
	SOUTHWEST IMPORT DISTRICT														
	REGIONAL LAB														
	REGIONAL STAFF														
PA	LOS ANGELES														
	SAN FRANCISCO														
	SEATTLE														
	PACIFIC REGIONAL LABORATORY-SW														
PACIFIC REGIONAL LABORATORY-NW															
HOURS PER OPERATION		23.0	4.2							22.0	8.5	16.0	6.6	11.7	17.3
TOTAL HOURS		460	5410							440	2465	4800	1835	702	692
CONVERSION FACTOR		950	950							1180	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.48	5.69							0.37	2.09	4.07	1.55	0.59	0.59
9. REMARKS															
* Inspections performed as F/U to violative dioxin samples															
The shaded area serves as a guideline for Districts on the specific types of samples that should be collected in order to match samples expected by the laboratories for analysis.															
**Domestic Sample Collection and Analysis: 71003E, sample collection and analysis are for pig ears, pet treats, and pet foods as well as other animal feed/ingredients.															
EXPECT THREE CENTER ASSIGNMENTS:															
1 Continuation of the assignment for collecting Direct Human Contact Feeds and analyzing for S salmonella. For more details please, see the assignment.															
2 Continuation of CFSAN/CVM assignment for Melamine in pet food/feed/feed ingredients [71R854]. For more details please, see the assignment.															
3 Antibiotics in distilled grains (DDG) for more details please see the assignment.															
Workload Source: FACTS database, firms in IND 69-72 with Workload Obligation of "YES" and Firm Status of "OPERATIONAL"															
NOTE: Continued on Page 71-4															

1 PROGRAM/ASSIGNMENT TITLE Feed Contaminants - IMPORT CONTINUED FROM PAGE 71-3						2 PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices -71						
3 PROGRAM/ASSIGNMENT CODE(S) 71003 A-K			4 WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> X ORA <input checked="" type="checkbox"/> X CENTER						5 OPERATIONAL FTE POSITIONS 4.0			
R E G I O N	0	4	4	4	4	0	0	0	0			
	DISTRICT/ SPECIALIZED LABORATORY	IMPORT SAMPLE COLL	IMPORT SAMPLE COLL Chem	IMPORT SAMPLE COLL Micro	IMPORT SAMPLE COLL Antibiotics	IMPORT FIELD EXAMS	IMPORT SAMPLE ANALYSIS Chem	IMPORT SAMPLE ANALYSIS Micro	IMPORT SAMPLE ANALYSIS Antibiotics			
	TOTAL FIELD	340	180	160	20	300	160	160	20			
	HEADQUARTERS	(b)(2)&(b)(7)(E)										
NE	REGIONAL STAFF	(b)(2)&(b)(7)(E)										
	NEW ENGLAND	(b)(2)&(b)(7)(E)										
	NEW YORK	(b)(2)&(b)(7)(E)										
	REGIONAL LAB	(b)(2)&(b)(7)(E)										
	WEAC	(b)(2)&(b)(7)(E)										
CE	REGIONAL STAFF	(b)(2)&(b)(7)(E)										
	BALTIMORE	(b)(2)&(b)(7)(E)										
	CHICAGO	(b)(2)&(b)(7)(E)										
	CINCINNATI	(b)(2)&(b)(7)(E)										
	DETROIT	(b)(2)&(b)(7)(E)										
	MINNEAPOLIS	(b)(2)&(b)(7)(E)										
	NEW JERSEY	(b)(2)&(b)(7)(E)										
	PHILADELPHIA	(b)(2)&(b)(7)(E)										
SE	REGIONAL STAFF	(b)(2)&(b)(7)(E)										
	ATLANTA	(b)(2)&(b)(7)(E)										
	FLORIDA	(b)(2)&(b)(7)(E)										
	NEW ORLEANS	(b)(2)&(b)(7)(E)										
	SAN JUAN	(b)(2)&(b)(7)(E)										
SW	REGIONAL LAB	(b)(2)&(b)(7)(E)										
	REGIONAL STAFF	(b)(2)&(b)(7)(E)										
	DALLAS	(b)(2)&(b)(7)(E)										
	DENVER	(b)(2)&(b)(7)(E)										
	KANSAS CITY	(b)(2)&(b)(7)(E)										
PA	SOUTHWEST IMPORT DISTRICT	(b)(2)&(b)(7)(E)										
	REGIONAL LAB	(b)(2)&(b)(7)(E)										
	REGIONAL STAFF	(b)(2)&(b)(7)(E)										
	LOS ANGELES	(b)(2)&(b)(7)(E)										
	SAN FRANCISCO	(b)(2)&(b)(7)(E)										
SEATTLE	(b)(2)&(b)(7)(E)											
	PACIFIC REGIONAL LABORATORY-SW	(b)(2)&(b)(7)(E)										
	PACIFIC REGIONAL LABORATORY-NW	(b)(2)&(b)(7)(E)										
	HOURS PER OPERATION	2.5				0.6	7.0	12.0	17.3			
	TOTAL HOURS	850				180	1120	1920	3480			
	CONVERSION FACTOR	950				950	1180	1180	1180.0			
	TOTAL OPERATIONAL FTEs	0.89				0.19	0.95	1.63	0.29			

9 REMARKS  
The shaded area serves as a guideline for Districts on the specific types of samples that should be collected in order to match samples expected by the laboratories for analysis

\*Import Sample Collection and Analysis: 71003E, sample collection and analysis are for pig ears, pet treats, and pet foods as well as other animal feed ingredients.

Workload Source: FACTS and OASIS databases.

1. PROGRAM/ASSIGNMENT TITLE Feed Manufacturing		2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71									
3. PROGRAM/ASSIGNMENT CODE(S) 71004 / A		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 4.5						
R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS FEED ESTABS	1 FOREIGN INSPECTIONS	3 DOMESTIC SAMPLE COLL	7 DOMESTIC SAMPLES ANALYZED (CHEM)	15 DOMESTIC SAMPLE COLL (GUIDE)					
	TOTAL FIELD	141	8	60	15	15					
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)									
	REGIONAL STAFF										
	NEW ENGLAND										
	NEW YORK										
	REGIONAL LAB										
WEAC											
CE	REGIONAL STAFF										
	BALTIMORE										
	CHICAGO										
	CINCINNATI										
	DETROIT										
	MINNEAPOLIS										
	NEW JERSEY										
	PHILADELPHIA										
FORENSIC CHEM. CTR											
SE	REGIONAL STAFF										
	ATLANTA										
	FLORIDA										
	NEW ORLEANS										
	REGIONAL LAB										
SW	REGIONAL STAFF										
	DALLAS										
	DENVER										
	KANSAS CITY										
	REGIONAL LAB										
PA	REGIONAL STAFF										
	LOS ANGELES										
	SAN FRANCISCO										
	SEATTLE										
	PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW											
HOURS PER OPERATION							22.0	40.0	6.5	39.0	
TOTAL HOURS							3102	320	390	585	
CONVERSION FACTOR							950	950	950	1180	
TOTAL OPERATIONAL FTEs							3.27	0.34	0.41	0.50	
9. REMARKS											
<p>*Resources are allocated for 15 physical samples, remaining resources may be used for the collection of documentary samples.</p> <p>Non-potency feed sample analysis should be charged to 71003 A/E.</p> <p>There are 339 State Contract inspections. Charge inspectional time for these contracts under 71S004.</p> <p>Resources for audit inspections are in the BSE program (71009) under "Technical Support" hours.</p> <p> Shaded area serves as a guideline for Districts on the specific types of samples that should be collected in order to match samples expected by the laboratories for analysis.</p> <p><u>Workload Source: Resource distribution is based on the CVM risk model for ranking firms in this program.</u></p>											

1. PROGRAM/ASSIGNMENT TITLE Illegal Residues in Meat & Poultry					2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71					
3. PROGRAM/ASSIGNMENT CODE(S) 71006, A. M			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 31.9			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	3	3	7	7	9	9
		TISSUE RESIDUE INSPEC- TIONS 71006	MILK RESIDUE INSPEC- TIONS 71006M ***	DOMESTIC SAMPLE COLL MILK 71006A	DOMESTIC SAMPLE COLL MILK 71006M ***	DOMESTIC SAMPLE COLL 71006 ****	DOMESTIC SAMPLES ANALYZED MILK 71006A **	DOMESTIC SAMPLES ANALYZED MILK 71006M ***	METHODS VALID (Hours)	TECH SUPPORT (HOURS)
<b>TOTAL FIELD</b>		400	180	200	180	415	400	180	360	1508
HEADQUARTERS		(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	NEW ENGLAND	(b)(2)&(b)(7)(E)								
	NEW YORK	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	WEAC	(b)(2)&(b)(7)(E)								
CE	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	BALTIMORE	(b)(2)&(b)(7)(E)								
	CHICAGO	(b)(2)&(b)(7)(E)								
	CINCINNATI	(b)(2)&(b)(7)(E)								
	DETROIT	(b)(2)&(b)(7)(E)								
	MINNEAPOLIS	(b)(2)&(b)(7)(E)								
	NEW JERSEY	(b)(2)&(b)(7)(E)								
	PHILADELPHIA	(b)(2)&(b)(7)(E)								
SE	FORENSIC CHEM. CTR	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	ATLANTA	(b)(2)&(b)(7)(E)								
	FLORIDA	(b)(2)&(b)(7)(E)								
	NEW ORLEANS	(b)(2)&(b)(7)(E)								
SW	SAN JUAN	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	DALLAS	(b)(2)&(b)(7)(E)								
	DENVER	(b)(2)&(b)(7)(E)								
PA	KANSAS CITY	(b)(2)&(b)(7)(E)								
	SOUTHWEST IMPORT DISTRICT	(b)(2)&(b)(7)(E)								
	REGIONAL LAB	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF	(b)(2)&(b)(7)(E)								
	LOS ANGELES	(b)(2)&(b)(7)(E)								
SAN FRANCISCO		(b)(2)&(b)(7)(E)								
SEATTLE		(b)(2)&(b)(7)(E)								
PACIFIC REGIONAL LABORATORY-SW		(b)(2)&(b)(7)(E)								
PACIFIC REGIONAL LABORATORY-NW		(b)(2)&(b)(7)(E)								
HOURS PER OPERATION		39.0	8.0	4.0	4.0	7.0	15.0	15.0		
TOTAL HOURS		15600.0	1440	800	720.0	2905	6000	2700	360	1508
CONVERSION FACTOR		950.0	950	950	950.0	950	1180	1180	1180	950
TOTAL OPERATIONAL FTEs		16.42	1.52	0.84	0.76	3.08	5.08	2.29	0.31	1.59
9. REMARKS										
<p>* Planned analytical time may be converted to methods development (including bridging methods) per CVM's concurrence. Methods development work will be assigned by CVM. Additional time for method validation and methods development studies.</p> <p>**Includes analysis time for 200 milk samples collected under state contracts.</p> <p>*** A separate milk sampling assignment includes inspections, sample collections, and analysis of milk samples.</p> <p>**** Documentary samples collected during inspections.</p> <p>† Tech Support hours include supporting state activities under Illegal Residues in Meat &amp; Poultry and time for Tissue Residue Monitors. Feed and Animal Drug samples are analyzed by Denver Laboratory.</p> <p>The Center will issue FACTS assignments to request Federal inspections when the risk score of the residue reported by FSIS exceeds the annually calculated budget-defined risk-informed threshold.</p> <p>Districts may issue assignments as well, but because resources for this program are limited, Districts should discuss issuing other assignments with CVM to determine if they fall within CVM priorities.</p> <p>Workload Source: Resource distribution is based on the CVM risk model for ranking residue violations in this program.</p>										

1. PROGRAM/ASSIGNMENT TITLE Ruminant Feed Ban Rule/BSE Program				2 PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds and Devices - 71										
3. PROGRAM/ASSIGNMENT CODE(S) 71009, 71R844, 71R843 (99R833, 71R833, 71R824)							<input checked="" type="checkbox"/> ORA		<input checked="" type="checkbox"/> CENTER		5. OPERATIONAL FTE POSITIONS 39.6 Domestic 27.4 Import 12.2			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 BSE INSP ECTI ONS *	2 DOMESTIC INVESTI GATION HOURS	2 IMPORT ENTRY REVIEW (Hours)	2 IMPORT INVESTI GATIONS (Hours) ***	3 DOMESTIC SAMPLE COLLECTI ONS	4 IMPORT FIELD EXAMS	4 IMPORT SAMPLE COLLECTI ONS ****	7 DOMESTIC SAMPLES ANALYZED CHEM	8 IMPORT SAMPLES ANALYZED	9 TECHNICAL SUPPORT (HOURS) **			
	<b>TOTAL FIELD</b>	1741	2670	7440	2030	855	3200	400	855	400	2748			
	HEADQUARTERS	(b)(2)&(b)(7)(E)												
NE	REGIONAL STAFF													
	NEW ENGLAND													
	NEW YORK													
	REGIONAL LAB													
	WEAC													
CE	REGIONAL STAFF													
	BALTIMORE													
	CHICAGO													
	CINCINNATI													
	DETROIT													
	MINNEAPOLIS													
	NEW JERSEY													
	PHILADELPHIA													
	FORENSIC CHEM. CTR													
SE	REGIONAL STAFF													
	ATLANTA													
	FLORIDA													
	NEW ORLEANS													
	SAN JUAN													
SW	REGIONAL LAB													
	REGIONAL STAFF													
	DALLAS													
	DENVER													
	KANSAS CITY													
PA	SOUTHWEST IMPORT DISTRICT													
	REGIONAL LAB													
	REGIONAL STAFF													
	LOS ANGELES													
	SAN FRANCISCO													
	SEATTLE													
	PACIFIC REGIONAL LAB - SW													
	PACIFIC REGIONAL LAB - NW													
<b>HOURS PER OPERATION</b>		7.5				4.0	0.4	2.5	6.0	4.3				
<b>TOTAL HOURS</b>		13058	2670	7440	2030	3420	1280	1000	5130	1720	2748			
<b>CONVERSION FACTOR</b>		950	950	1200	950	950	950	950	1180	1180	950			
<b>TOTAL OPERATION FTEs</b>		13.74	2.81	6.20	2.14	3.80	1.35	1.05	4.35	1.48	2.89			
7. REMARKS  * Inspections of performance goal firms with establishment types for renderers, protein blenders, and feed mills should be covered once per year, and other establishment types handling or not handling prohibited material as specified in the inspectional priorities listed on the next page.  <u>Workload Distribution: Resource distribution based on the CVM risk model for ranking firms in this program.</u>  ** Technical support hours include supporting state activities under the Ruminant Feed Ban Regulation and supporting state activities under the Feed Manufacturing Program (71004). These hours also include resources for audits of state contract inspections and BSE partnerships.  Domestic Investigation Hours are to be utilized for OEI Improvement with a focus on searching for new firms that fall under the high risk category. Report CVM State Contract Inspection Audit time under 71R843 Operation 13 (Investigation Operations)  *** Import Investigation Hours are for filer evaluations, follow-up to refusals, and other operations as required by the District to cover program priorities. Districts should report time under the appropriate Operation and PAC for the activities performed.  <b>Reporting Guidance:</b> Import Entry Review (Electronic and Manual—Operation Code 14, PAC 71R833); Filer Evaluations (Operation Code 95, PAC 99R833); and Follow-up to Refused Import Entries (PAC 71R824).														

## CONTINUATION SHEET

1 PROGRAM/ASSIGNMENT TITLE

Ruminant Feed Ban Rule/BSE Program

2. PPS PROJECT NAME/NUMBER

Monitoring of Marketed Animal Drugs Feeds and Devices - 71

**Inspection Priorities.**

The first inspectional priority under this program is to inspect those firms that have a violative history that have been classified by the FDA as "Official Action Indicated" or OAI. These inspections should be conducted with the intent that regulatory action will be pursued should the firm be unwilling or unable to take immediate actions to correct the violations. 21 CFR §589.2000 pertains to a variety of firms and animal production operations that involve the manufacture, distribution, transportation, and feeding of animal feeds. Although the intent of the rule is to ensure that specified animal proteins are not fed to ruminant animals, the regulation is written broadly in such a way as to include some operations that do not necessarily involve ruminant feeds or the feeding of ruminant animals. Inspectional resources for surveillance are to be spent covering those firms or industries potentially having the most adverse affect on BSE prevention efforts should non-compliance with the regulations be encountered. In planning and prioritizing inspections, the following firm/industry types should be considered, in order of descending priority:

- Follow-up to 'OAI' inspections
- Firms that have a violative
- Firms handling prohibited materials (Renderers, Protein Blenders, and Feed Mills)
- Rendering operations
- Protein Blenders
- Commercial feed mills (licensed and unlicensed)
- Animal feed distributors/retailers (ruminant feeds involved)
- Pet food/animal feed salvage operations
- On-farm feed mixers (ruminant and non-ruminant animals on farm premises)
- Haulers/transporters of animal feeds (ruminant feeds involved)
- Ruminant feeders (dairy cattle)
- Ruminant feeders (ruminants other than dairy cattle)
- Animal feed distributors/retailers (no ruminant feeds involved)
- Haulers/transporters of animal feeds (no ruminant feeds involved)
- On-farm feed mixers (only ruminant or no ruminant animals on farm premises)

1. PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program			2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71			
3. PROGRAM/ASSIGNMENT CODE(S) 71R816			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER		5. OPERATIONAL FTE POSITIONS 5.0	
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	METHODS VAL/DEV CHEM (Hours)	APPLIED TECHNOLOGY CENTER CHEM (Hours)			
		TOTAL FIELD	1205	4720		
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)				
	REGIONAL STAFF					
	NEW ENGLAND					
	NEW YORK					
	REGIONAL LAB					
CE	WEAC					
	REGIONAL STAFF					
	BALTIMORE					
	CHICAGO					
	CINCINNATI					
	DETROIT					
	MINNEAPOLIS					
	NEW JERSEY					
SE	PHILADELPHIA					
	FORENSIC CHEM. CTR					
	REGIONAL STAFF					
	ATLANTA					
	FLORIDA					
SW	NEW ORLEANS					
	SAN JUAN					
	REGIONAL LAB					
	REGIONAL STAFF					
	DALLAS					
PA	DENVER					
	KANSAS CITY					
	SOUTHWEST IMPORT DISTRICT					
	REGIONAL LAB					
	REGIONAL STAFF					
HOURS PER OPERATION						
TOTAL HOURS		1205	4720			
CONVERSION FACTOR		1205	1180			
TOTAL OPERATIONAL FTEs		1.00	4.00			
9. REMARKS  Workload Source: Determined by Division of Field Science, ORO.						

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Forensic Evaluation and Sample Analysis		<b>2. PPS PROJECT NAME/NUMBER</b> Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71							
<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 71R838		<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER		<b>5. OPERATIONAL FTE POSITIONS</b> 1.0					
R E G I O N	<b>6. DISTRICT/SPECIALIZED LABORATORY</b>	<b>FORENSIC ANALYSIS CHEM (Hours)</b>							
	<b>TOTAL FIELD</b>	1205							
	HEADQUARTERS	(b)(2)&							
	REGIONAL STAFF	(b)(7)(E)							
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
CE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
SW	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
PA	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	<b>HOURS PER OPERATION</b>								
	<b>TOTAL HOURS</b>	1205							
	<b>CONVERSION FACTOR</b>	1205							
	<b>TOTAL OPERATIONAL FTEs</b>	1.00							
<b>9. REMARKS</b>									

1. PROGRAM/ASSIGNMENT TITLE Center Initiated Assignments	2. PPS PROJECT NAME/NUMBER Monitoring of Marketed Animal Drugs, Feeds, and Devices - 71
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3. PROGRAM/ASSIGNMENT CODE(S) 71V800	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.0
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R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	2 INVESTI- GATIONS 71V800 (Hours)								
	<b>TOTAL FIELD</b>	950								
	HEADQUARTERS	(b)(2)&								
NE	REGIONAL STAFF	(b)(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION									
	TOTAL HOURS	950								
	CONVERSION FACTOR	950								
	TOTAL OPERATIONAL FTEs	1.00								

9. REMARKS

These resources include time for investigating pel turtle establishments, and to inspect pharmacies compounding animal products.

71V800: Workload Source: Based on a pro-rated inventory in Feed Manufacturing, Feed Contaminants and Pre-Approval programs.

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH  
RESOURCE SUMMARY  
FY 2010**

PPS NO.	PROJECT TITLE	OPERATIONAL FTES			TOTAL OPERATIONAL FTEs
		DOMESTIC	IMPORT	FOREIGN	
	<b>TOTAL</b>	<b>174.4</b>	<b>56.1</b>	<b>25.5</b>	<b>256.0</b>
81	POSTMARKET ASSURANCE: DEVICES	0.5			0.5
82	COMPLIANCE: DEVICES	102.7	48.6	19.8	170.9
83	PRODUCT EVALUATION: DEVICES	31.2		3.8	35.0
84	SCIENCE: DEVICES	4.7			4.7
85	MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA) AUTHORITY	14.5		0.1	14.6
86	RADIATION CONTROL AND HEALTH SAFETY ACT (RCHSA) AUTHORITY	20.8	7.5	2.0	30.3



1. PROGRAM/ASSIGNMENT TITLE Medical Device Problem Reporting - MDR Follow-Up					2. PPS PROJECT NAME/NUMBER Postmarket Assurance: Devices - 81				
3. PROGRAM/ASSIGNMENT CODE(S) 81010			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 0.5			
R E G I O N	8. DISTRICT/ SPECIALIZED LABORATORY	1	2	3	3	3	7	7	7
		INSP CTIONS  (1)	INVESTI GATIONS (Hours)  (2)	DOMESTIC SAMPLE COLL ENG	DOMESTIC SAMPLE COLL CHEM	DOMESTIC SAMPLE COLL STER	DOMESTIC SAMPLES TO BE ANALYZED ENG (3)	DOMESTIC SAMPLES TO BE ANALYZED CHEM (4)	DOMESTIC SAMPLES TO BE ANALYZED STER (6)
<b>TOTAL FIELD</b>		<b>22</b>	<b>16</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>
HEADQUARTERS (b)(2)&(b)(7)(E)									
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION		15.0		10.3	10.3	10.3	37.0	36.0	20.0
TOTAL HOURS		343	16	10	10	10	37	36	20
CONVERSION FACTOR		950	950	950	950	950	1180	1180	1180
TOTAL OPERATIONAL FTEs		0.36	0.02	0.01	0.01	0.01	0.03	0.03	0.02
9. REMARKS									
<p>(1) Inspections may be based on direct Center assignment, as a result of receiving problem reports which are significant, or when a defect, injury, or death that has been reported directly to a district requires followup.</p> <p>(2) Investigational hours for MDR followup at medical facilities.</p> <p>(3) MDR samples to confirm reported defects.</p> <p>(4) Performance testing of chemical and serological test kits.</p> <p>(5) Sterility testing to confirm reports of defective packaging and gross bacterial contamination of filth.</p>									



1. PROGRAM/ASSIGNMENT TITLE Monitoring Devices of Foreign Origin - Import	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82008, 82R824, 82R833, 99R833	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 38.5
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R E G I O N	B. DISTRICT/ SPECIALIZED LABORATORY		2	2	4	4	4	8	8
			ENTRY REVIEW (Hours)	IMPORT INV HOURS *	IMPORT FIELD EXAMS CONGRESSIONAL TARGET	IMPORT SAMPLE COLL (Physical) ENG	IMPORT SAMPLE COLL (Physical) MICRO **	IMPORT SAMPLES TO BE ANALYZED ENG	IMPORT SAMPLES TO BE ANALYZED MICRO ***
	<b>TOTAL FIELD</b>		26528	3912	12780	60	60	60	60
	HEADQUARTERS		(b)(2)&(b)(7)(E)						
	REGIONAL STAFF								
NE	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
	REGIONAL STAFF								
CE	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
SE	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
PA	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
	<b>HOURS PER OPERATION</b>		0.7	2.2	2.2	25.5	25.5		
	<b>TOTAL HOURS</b>	26528	3912	8946	132	132	1530	1530	
	<b>CONVERSION FACTOR</b>	1200	950	950	950	950	1180	1180	
	<b>TOTAL OPERATIONAL FTEs</b>	22.11	4.12	9.42	0.14	0.14	1.30	1.30	

9. REMARKS

\* Import investigation hours are for field exams (non-Congressional Target), filer evaluations, follow-up to refusals, label exams, and other operations as required by the District to cover program priorities. Districts should report time under the appropriate operation and PAC for the activities performed. Field Exams to meet Congressional Targets are planned in a separate column.

\*\* Audit samples for problems other than failure to register or list (eg. special assignment, import alert). Includes 19 samples (40 subs each) of devices labeled as sterile; selection to be made by the import district.

\*\*\* Sterile devices to be tested by USP XX method. Includes 19 samples (40 subs each) of devices labeled as sterile; selection to be made by the import district.

Reporting Guidance:

- Import Entry Reviews (Electronic and Manual—operation code 14, PAC 82R833);
- Filer Evaluations (operation code 95, PAC 99R833); and
- Follow-up to Refusals (PAC 82R824).

Counter Terrorism PAC 82R845 is no longer used for planning purposes, but is still active for reporting purposes.

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers				2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82						
3. PROGRAM/ASSIGNMENT CODE(S) 82845A,B,C,G,J,K,P,S, 81845R,T, 81011			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 118.0 [115.1]			
REG ION	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	1	1	2	2
		INSPEC- TIONS LEVEL I DOMESTIC 82845A	INSPEC- TIONS LEVEL II DOMESTIC 82845B	INSPEC- TIONS LEVEL III COMPLIANCE DOMESTIC 82845C	INSPEC- TIONS FOREIGN 82845B	INSPEC- TIONS FOR CAUSE DOMESTIC 82845G	INSPEC- TIONS FOR CAUSE HIGH RSK DOMESTIC 82845G	INSPEC- TIONS ACCRED PERSONS DOMESTIC 82845P	INVESTI- GATIONS (Hours) 82845B	INVESTI- GATIONS (Hours) A.P. AUDITS MDUFMA 82845J
TOTAL FIELD		782	528	108	286	75	75	7	3309	255
HEADQUARTERS (b)(2)&(b)(7)(E)										
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
SEATTLE										
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		39.7	62.5	100.0	65.0	71.0	90.0	63.0		
TOTAL HOURS		31045	33000	10800	18590	5325	8750	441	3309	255
CONVERSION FACTOR		950	950	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		32.68	34.74	11.16	19.57	5.61	7.11	0.46	3.48	0.27

9. REMARKS  
**For FY 2010, the hours/operation module for Level I inspections has been planned at 39.7 hours/operation to include additional time for MDR review. Level II inspection hours/operation modules have also been adjusted to reflect actual work.**  
 Quality Systems Inspection Technique (QSIT) inspection time has been planned for Level 1 (82845A), Level 2 (82845B), Level 3 (82845C) and "For Cause" (82845G) inspections. We cannot accurately plan the number of Level 3 (compliance follow up) and "for cause" inspections each district will conduct based on the criteria established in the program. The number of inspections reflected in each of these areas is based upon historical data. Reprogram any unused resources into Level 1 and 2 inspections.  
 Inspectional modules include time for 82845S (sterilization), MDR (81001), Corrections and Removals (81845R), Tracking (81845T), and Registration and Listing. Resources for Single Use Reprocessor inspections have been included in Level 2 Inspections. Investigational Hours resources have also been planned for National Experts (HQ line) and State Contract Monitoring (DAL-DO line).  
 Foreign inspections include resources for Level I, II, III, and For Cause-related inspections. For planning purposes Foreign inspections will be planned under the Level II inspection PAC (82845B); use the appropriate reporting PAC to record accomplishments associated with these Foreign inspections.  
 Accredited Person inspections are based on estimates of numbers and locations and are not based on known factors. Therefore, resources not used in that MDUFMA program should be planned as statutory GMP Inspections. If additional audits not covered by the workplan are required, resources can be taken from the general GMP program. Accredited Person Audits are conducted by NWE-DO, MIN-DO, SJN-DO, KAN-DO, SEA-DO.

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82845A,B,C,G,J,K,P,S, 81845R,T, 81011	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 118.0 [2.5]
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R E G I O N	DISTRICT/ SPECIALIZED LABORATORY	3	3	3	3	7	7	7		
		DOMESTIC SAMPLE COLL ENG 82845C	DOMESTIC SAMPLE COLL ENG 82846C	DOMESTIC SAMPLE COLL MICRO 82845C	DOMESTIC SAMPLE COLL CHEM 82846C	DOMESTIC SAMPLES TO BE ANALYZED ENG 82845C	DOMESTIC SAMPLES TO BE ANALYZED MICRO 82845C	DOMESTIC SAMPLES TO BE ANALYZED CHEM 82845C		
	TOTAL FIELD	42	10	26	6	10	28	6		
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
NE	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	6.0				80.0	62.0	38.0		
	TOTAL HOURS	252				800	1612	228		
	CONVERSION FACTOR	950				1180	1180	1180		
	TOTAL OPERATIONAL FTEs	0.27				0.68	1.37	0.18		

9. REMARKS

NOTE: Unshaded columns, for all Domestic Sample Collections, will include Documentary Samples; refer to shaded columns for those specific types of analyses that will be associated with the Domestic Samples collected.

MICRO Sample Analyses: Antisera and Products Media Testing to support GMP observations at WEAC; Disinfectant/Cold Sterilant Testing at WEAC and DEN Lab.

CHEM Sample Analyses: Test Kit or Reagent Testing to support GMP observations at WEAC; Sporicidal and Tuberculocidal at WEAC and DEN Lab.

1. PROGRAM/ASSIGNMENT TITLE Inspection of Medical Device Manufacturers	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82845A,B,C,G,J,K,P,S, 81845R,T, 81011	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 118.0 [0.4]
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	6. DISTRICT/ SPECIALIZED LABORATORY	3 DOMESTIC SAMPLE COLL #2845S	3 DOMESTIC SAMPLE COLL BIOBURDEN BIOINDICATOR #2845S	3 DOMESTIC SAMPLE COLL STERILITY #2845S	7 DOMESTIC SAMPLES TO BE ANALYZED BIOBURDEN #2845S	7 DOMESTIC SAMPLES TO BE ANALYZED STERILITY #2845S							
	<b>TOTAL FIELD</b>	15	10	5	10	5							
R E G I O N	HEADQUARTERS	(b)(2)&(b)(7)(E)											
	REGIONAL STAFF												
NE	NEW ENGLAND												
	NEW YORK												
	REGIONAL LAB												
	WEAC												
	REGIONAL STAFF												
CE	BALTIMORE												
	CHICAGO												
	CINCINNATI												
	DETROIT												
	MINNEAPOLIS												
	NEW JERSEY												
	PHILADELPHIA												
FORENSIC CHEM. CTR													
SE	REGIONAL STAFF												
	ATLANTA												
	FLORIDA												
	NEW ORLEANS												
	SAN JUAN												
SW	REGIONAL LAB												
	REGIONAL STAFF												
	DALLAS												
	DENVER												
	KANSAS CITY												
PA	SOUTHWEST IMPORT DISTRICT												
	REGIONAL LAB												
	REGIONAL STAFF												
	LOS ANGELES												
	SAN FRANCISCO												
	SEATTLE												
	PACIFIC REGIONAL LABORATORY-SW												
	PACIFIC REGIONAL LABORATORY-NW												
	<b>HOURS PER OPERATION</b>	4.7			25.0	29.5							
	<b>TOTAL HOURS</b>	71			250	148							
	<b>CONVERSION FACTOR</b>	950			1180	1180							
	<b>TOTAL OPERATIONAL FTEs</b>	0.07			0.21	0.13							

8. REMARKS

NOTE: Unshaded columns, for all Domestic Sample Collections, will include Documentary Samples; refer to shaded columns for those specific types of analyses that will be associated with the Domestic Samples collected.

Note: Domestic Sample Collections for Bioburden, Bioindicator are to be collected "for cause".

Domestic Sample Collections for Contract Sterilizers are to be collected "for cause".

1. PROGRAM/ASSIGNMENT TITLE Condom Assignment	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82Z002	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 3.6
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS			4 IMPORT SAMPLE COLL CHEM (PHYSICAL)			8 IMPORT SAMPLES TO BE ANALYZED CHEM (PHYSICAL)
	<b>TOTAL FIELD</b>	<b>3</b>			<b>266</b>			<b>266</b>
NE	HEADQUARTERS	(b)(2)&(b)			(b)(2)&(b)			(b)(2)&(b)
	REGIONAL STAFF	(7)(E)			(7)(E)			(7)(E)
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
	WEAC							
CE	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
	PHILADELPHIA							
SE	FORENSIC CHEM. CTR							
	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
	NEW ORLEANS							
SW	SAN JUAN							
	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
	DENVER							
	KANSAS CITY							
PA	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
	REGIONAL STAFF							
	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
PACIFIC REGIONAL LABORATORY-SW								
PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION		24.0			2.3			12.8
TOTAL HOURS		72			812			3405
CONVERSION FACTOR		950			950			1180
TOTAL OPERATIONAL FTEs		0.08			0.64			2.89

9. REMARKS  
 Import Samples are estimated and should be collected to cover the districts' workload. Resources for Condom Detentions Without Physical Exam requests, part of the Entry Review process for entries covered by the Import Alert, are included as Import Entry Review Hours in PAC 82008 - Monitoring Devices of Foreign Origin. Reporting Guidance: Import Entry Reviews (Electronic & Manual—operation code 14, PAC 82R833); Filer Evaluations (operation code 95, PAC 99R833); and Follow-up to Refusals (PAC 82R824).

1. PROGRAM/ASSIGNMENT TITLE Manufacturers and Importers of Surgical/Examination Gloves				2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82					
3. PROGRAM/ASSIGNMENT CODE(S) 82Z003			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 7.5			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY				4	4	8	8	9
					IMPORT SAMPLE COLL ENG (PHYSICAL)	IMPORT SAMPLE COLL CHEM (PHYSICAL)	IMPORT SAMPLES TO BE ANALYZED ENG (PHYSICAL)	IMPORT SAMPLES TO BE ANALYZED CHEM (PHYSICAL)	OTHER OPERATIONS (Hours) ENG
	TOTAL FIELD				194	565	194	565	1180
NE	HEADQUARTERS				(b)(2)&(b)(7)(E)		(b)(2)&(b)(7)(E)		
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
SE	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
SW	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
PA	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
PA	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION					2.1	2.1	7.5	7.5	
TOTAL HOURS					407	1187	1455	4238	1180
CONVERSION FACTOR					950	950	1180	1180	1180
TOTAL OPERATIONAL FTEs					0.43	1.25	1.23	3.59	1.00
9. REMARKS									
Resources to cover Glove Detentions Without Physical Exam requests, part of the Entry Review process for entries covered by the Import Alert, are included as Import Entry Review Hours in PAC 82008 - Monitoring Devices of Foreign Origin.									
Reporting Guidance: Import Entry Reviews (Electronic & Manual—operation code 14, PAC 82R833); Filer Evaluations (operation code 95, PAC 99R833); and Follow-up to Refusals (PAC 82R824).									
Other Operations (Hours) are for Private Lab Review Technical Assistance/Coordination at WEAC: Review time must be reported under Miscellaneous Operation Code 92 with "PL" in the FACTS description field; without this consistency in reporting, your time will not be found and credited.									

1. PROGRAM/ASSIGNMENT TITLE Center Initiated Assignments	2. PPS PROJECT NAME/NUMBER Compliance: Devices - 82
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3. PROGRAM/ASSIGNMENT CODE(S) 82Z005, 82Z800	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5. OPERATIONAL FTE POSITIONS 1.0
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY		1 INSPEC- TIONS CENTER- INITIATED 82Z800	3 DOMESTIC SAMPLE COLL (1) 82Z800	7 DOMESTIC SAMPLES TO BE ANALYZED CHEM (2) 82Z800	7 DOMESTIC SAMPLES TO BE ANALYZED STERILITY(3) 82Z800	7 DOMESTIC SAMPLES TO BE ANALYZED MICRO (4) 82Z800	9 OTHER OPERATIONS (Hours) METH DEV ENG (6) 82Z800
	<b>TOTAL FIELD</b>		6	14	1	2	2	400
NE	HEADQUARTERS		(b)(2)&(b)(7)(E)	(b)(2)&(b)(7)(E)				(b)(2)&(b)(7)(E)
	REGIONAL STAFF		(7)(E)					
	NEW ENGLAND							
	NEW YORK							
	REGIONAL LAB							
CE	WEAC							
	REGIONAL STAFF							
	BALTIMORE							
	CHICAGO							
	CINCINNATI							
	DETROIT							
	MINNEAPOLIS							
	NEW JERSEY							
SE	PHILADELPHIA							
	FORENSIC CHEM. CTR							
	REGIONAL STAFF							
	ATLANTA							
	FLORIDA							
SW	NEW ORLEANS							
	SAN JUAN							
	REGIONAL LAB							
	REGIONAL STAFF							
	DALLAS							
PA	DENVER							
	KANSAS CITY							
	SOUTHWEST IMPORT DISTRICT							
	REGIONAL LAB							
	REGIONAL STAFF							
PA	LOS ANGELES							
	SAN FRANCISCO							
	SEATTLE							
	PACIFIC REGIONAL LABORATORY-SW							
	PACIFIC REGIONAL LABORATORY-NW							
	HOURS PER OPERATION		55.0	10.0	15.0	50.0	50.0	
	TOTAL HOURS		330	140	15	100	100	400
	CONVERSION FACTOR		850	950	1180	1180	1180	1180
	TOTAL OPERATIONAL FTEs		0.35	0.15	0.01	0.08	0.08	0.34

9. REMARKS  
 Planned BSE Inspections (82Z005) were cancelled in FY 2008; PAC will remain active for reporting purposes and any Center-Initiated Assignments involving BSE should be reported in PAC 82Z005.

(1) Includes Documentary Samples and Analytical Samples.  
 (2) WEAC—Ad Hoc testing of test kits or reagents.  
 (3) WEAC—Sterility samples.  
 (4) WEAC—Ad Hoc testing of media.  
 (5) WEAC—Misc hours for engineers; includes Voluntary Standards Assessment and Methods Development.



<b>1 PROGRAM/ASSIGNMENT TITLE</b> Forensic Evaluation and Sample Analysis	<b>2 PPS PROJECT NAME/NUMBER</b> Compliance: Devices - 82
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<b>3 PROGRAM/ASSIGNMENT CODE(S)</b> 82R838	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	<b>5 OPERATIONAL FTE POSITIONS</b> 0.3
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R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	FORENSIC ANALYSIS CHEM (Hours)								
	<b>TOTAL FIELD</b>	<b>360</b>								
	HEADQUARTERS	(b)(2)&(b)								
NE	REGIONAL STAFF	(7)(E)								
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM. CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
SW	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
PA	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	<b>HOURS PER OPERATION</b>									
	<b>TOTAL HOURS</b>	<b>360</b>								
	<b>CONVERSION FACTOR</b>	<b>1205</b>								
	<b>TOTAL OPERATIONAL FTEs</b>	<b>0.30</b>								

9. REMARKS



1. PROGRAM/ASSIGNMENT TITLE Medical Device Premarket Approval and Postmarket Inspections			2. PPS PROJECT NAME/NUMBER Product Evaluation: Devices - 83							
3. PROGRAM/ASSIGNMENT CODE(S) 83001, A		4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 9.7					
R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS POST- APPROVAL 83001A	1 FOREIGN INSPEC- TIONS PRE- APPROVAL 83001	1 FOREIGN INSPEC- TIONS POST- APPROVAL 83001A	1 INSPEC- TIONS MDUFMA USER FEE 83001					
	TOTAL FIELD	49	32	21	67					
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
WEAC										
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
FORENSIC CHEM. CTR										
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
REGIONAL LAB										
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
REGIONAL LAB										
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION						41.0	50.0	41.0	71.0	
TOTAL HOURS						2009	1600	881	4757	
CONVERSION FACTOR						950	950	950	950	
TOTAL OPERATIONAL FTEs						2.11	1.68	0.91	5.01	
9. REMARKS Report all time used for evaluating compliance with <u>domestic</u> pre-market requirements in PAC 83001, OP CODE 12; report all time used for <u>domestic</u> post-market requirements in PAC 83001A, OP CODE 12.  Report all time used for evaluating compliance with <u>foreign</u> pre-market requirements in PAC 83001, OP CODE 11; report all time used for <u>foreign</u> post-market requirements in PAC 83001A, OP CODE 11.										

<b>1. PROGRAM/ASSIGNMENT TITLE</b> Bioresearch Monitoring (Pre-Market)	<b>2. PPS PROJECT NAME/NUMBER</b> Product Evaluation: Devices - 83
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<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 83808, 83809, 83810, 83811	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	<b>5. OPERATIONAL FTE POSITIONS</b> 25.3
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R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	1 INSPEC- TIONS DOMESTIC	1 INSPEC- TIONS FOREIGN							
	<b>TOTAL FIELD</b>	<b>305</b>	<b>15</b>							
	HEADQUARTERS	(b)(2)&(b)(7)(E)								
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
SW	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
	DENVER									
PA	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	<b>HOURS PER OPERATION</b>	75.1	75.1							
	<b>TOTAL HOURS</b>	22906	1127							
	<b>CONVERSION FACTOR</b>	950	950							
	<b>TOTAL OPERATIONAL FTEs</b>	24.11	1.19							

**9. REMARKS**  
 Device Bioresearch Monitoring inspections should be prioritized according to the following scheme:  
 1) For Cause with 30-day due dates;  
 2) Directed data audit for expedited PMA;  
 3) Directed data audit for non-expedited PMA;  
 4) For Cause with 60-90 day due dates;  
 5) OAI Follow-up (6 months);  
 6) Early Intervention (Probability Sampling, Vulnerable Population, and IDE-based)  
 7) Routine Surveillance.

Please contact Ruth Hinckley (301-796-5658) or Matthew Tarosky (301-796-5645) with any questions.



1. PROGRAM/ASSIGNMENT TITLE Test Method Development and Evaluation				2. PPS PROJECT NAME/NUMBER Science: Devices - 84					
3. PROGRAM/ASSIGNMENT CODE(S) 84Z002			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 3.7			
R E G I O N	6. DISTRICT/SPECIALIZED LABORATORY						8 OTHER OPERATIONS (Hours) METH DEV MICRO	9 OTHER OPERATIONS (Hours) METH DEV ENG	
	TOTAL FIELD						800	3590	
NE	HEADQUARTERS						(b)(2)&(b)(7)(E)		
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
WEAC									
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
SE	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
SW	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
PA	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
SAN FRANCISCO									
SEATTLE									
PACIFIC REGIONAL LABORATORY-SW									
PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION									
TOTAL HOURS						800			3590
CONVERSION FACTOR						1180			1180
TOTAL OPERATIONAL FTEs						0.68			3.04
9. REMARKS Above resources are for participation in the development of test methods and testing protocol. Projects will be coordinated by the CDRH Laboratory Staff.									

1 PROGRAM/ASSIGNMENT TITLE Methods Validation/Development Program	2. PPS PROJECT NAME/NUMBER Science: Devices - 84
--	---

3 PROGRAM/ASSIGNMENT CODE(S) 84R816	4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER	5 OPERATIONAL FTE POSITIONS 1.0
--	--	------------------------------------

R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	APPLIED TECHNOLOGY CENTER MICRO (Hours)							
	<b>TOTAL FIELD</b>	<b>1180</b>							
	HEADQUARTERS	(b)(2)&(b) (7)(E)							
NE	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
	WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
	FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
PA	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
PACIFIC REGIONAL LABORATORY-NW									
HOURS PER OPERATION									
TOTAL HOURS			1180						
CONVERSION FACTOR			1180						
TOTAL OPERATIONAL FTEs			1.00						

9. REMARKS

Workload Source: Determined by Division of Field Science, ORO.



1. PROGRAM/ASSIGNMENT TITLE Mammography Facilities Inspection Program				2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85													
3. PROGRAM/ASSIGNMENT CODE(S) 85014 A,C,F			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 14.6 [8.6]										
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	1	1	2	2								
		INSPEC- TIONS 85014 (1)	INSPEC- TIONS FOREIGN 85014 (2)	INSPEC- TIONS 85014 (3)	INSPEC- TIONS 85014 (4)	INSPEC- TIONS 85014F (5)	INSPEC- TIONS 85014F (6)	INVESTI- GATIONS (Hours) 85014A (7)	OTHER OPERATIONS (Hours) 85014C (8)								
	TOTAL FIELD	220	15	121	33	9	9	2200	4466								
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)															
	REGIONAL STAFF																
	NEW ENGLAND																
	NEW YORK																
	REGIONAL LAB																
WEAC																	
CE	REGIONAL STAFF																
	BALTIMORE																
	CHICAGO																
	CINCINNATI																
	DETROIT																
	MINNEAPOLIS																
	NEW JERSEY																
	PHILADELPHIA																
SE	FORENSIC CHEM. CTR																
	REGIONAL STAFF																
	ATLANTA																
	FLORIDA																
	NEW ORLEANS																
SW	SAN JUAN																
	REGIONAL LAB																
	REGIONAL STAFF																
	DALLAS																
	DENVER																
PA	KANSAS CITY																
	SOUTHWEST IMPORT DISTRICT																
	REGIONAL LAB																
	REGIONAL STAFF																
	LOS ANGELES																
SAN FRANCISCO																	
SEATTLE																	
PACIFIC REGIONAL LABORATORY-SW																	
PACIFIC REGIONAL LABORATORY-NW																	
HOURS PER OPERATION										8.0	8.0	8.0	8.0	11.0	11.0		
TOTAL HOURS										1780	120	986	284	99	99	2200	4466
CONVERSION FACTOR										1180	1180	1180	1180	1180	1180	1180	1180
TOTAL OPERATIONAL FTEs										1.52	0.10	0.83	0.23	0.09	0.09	1.90	3.85
9. REMARKS <b>RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE &amp; COORDINATION HOURS</b> 1) Inspection of Certified Mammography Facilities not covered by the states. 2) Inspection of Domestic Establishment Mammography Facilities in Foreign Countries. 3) Federal Facility Inspections (does not include VHA Facility inspections). 4) VHA Facility Inspections. 5) Follow-up Inspections. 6) Follow-up Inspection after Warning Letter. 7) Audit Investigations. 8) Compliance Activities: Inspection Follow-Up Activities (Non-Warning Letter).																	

1. PROGRAM/ASSIGNMENT TITLE Mammography Facilities Inspection Program					2. PPS PROJECT NAME/NUMBER Mammography Quality Standards Act (MQSA) Authority - 85				
3. PROGRAM/ASSIGNMENT CODE(S) 85014 A,C,F			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 14.6 [6.0]			
R E G I O N	B. DISTRICT/ SPECIALIZED LABORATORY						9	9	9
							OTHER OPERATIONS (Hours) 85014C (8)	OTHER OPERATIONS (Hours) 85014C (10)	OTHER OPERATIONS (Hours) 85014C (11)
	TOTAL FIELD						1200	5730	59
NE	HEADQUARTERS						(b)(2)&(b)(7)(E)		
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
CE	WEAC								
	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
SE	PHILADELPHIA								
	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
SW	NEW ORLEANS								
	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
PA	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
PA	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW								
	PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION									
TOTAL HOURS							1200	5730	59
CONVERSION FACTOR							1200	1180	1180
TOTAL OPERATIONAL FTEs							1.00	4.94	0.05

9. REMARKS  
**RRHRs SHOULD REPORT ALL TECHNICAL ASSISTANCE & COORDINATION HOURS**

9) Technical Assistance and Coordination Activities: RRHRs.  
 10) Technical Assistance and Coordination Activities: non-RRHRs.  
 11) Compliance Activities: Warning Letters.

# PROJECT SUMMARY SHEET

FY 2010

1. PROGRAM CATEGORY		2. PPS PROJECT NAME/NUMBER					
Medical Devices and Radiological Health		Radiation Control and Health Safety Act (RCHSA) Authority - 86					
3. No.	4. FDA COMPLIANCE PROGRAMS AND ASSIGNMENTS	5. PROGRAM ASSIGNMENT CODE	6. OPERATIONAL FTE			7. TOTAL OPERATIONAL FTEs	8. PAGE
			DOMESTIC	IMPORT	FOREIGN		
	<b>TOTAL</b>		20.8	7.5	2.0	30.3	
1	Inspection and Field Testing of Radiation-Emitting Electronic Products:		5.1		0.2	5.3	86-23-4
	Inspection of Manufacturers of Laser Products	86001	(4.3)		(0.2)	(4.5)	
	Field Implementation of the Sunlamp & Sunlamp Products Performance Standard as Amended	86002	(0.3)			(0.3)	
	Field Compliance Testing of Cabinet X-Ray Equipment	86004	(0.5)			(0.5)	
2	Inspections of Manufacturers (Foreign and Domestic) and Field Compliance Testing of Diagnostic X-Ray Equipment	86003	7.6		1.0	8.6	86-25-30
3	Compliance Testing of Electronic Products at WEAC	86006, A, B, D, E	3.1		0.8	3.9	86-31
4	Imported Electronic Products	86007 *		7.5		7.5	86-32
5	Radiological Health Control Activities:		5.0			5.0	86-33-4
	Medical Device and Radiological Health Use Control and Policy Implementation	86008	(3.0)			(3.0)	
	Emergency Planning and Response Activities	86009	(2.0)			(2.0)	
	* In addition to PAC 86007, includes reporting PACs 86R824, 86R833, and 99R833.						

CENTER PROJECT MANAGER/TELEPHONE  
Lynne L. Rice 240-276-3209

ORA PLANNER/TELEPHONE  
John Aydinian 301-796-4394

1 PROGRAM/ASSIGNMENT TITLE Inspection and Field Testing of Radiation-Emitting Electronic Products					2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86					
3. PROGRAM/ASSIGNMENT CODE(S) 86001, 86002, 86004			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5 OPERATIONAL FTE POSITIONS 5.3			
R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY	1	1	1	1	2	2	3	5	5
		INSP EC T I O N S  86001 (1)	INSP EC T I O N S F O R E I G N  86001 (2)	INSP EC T I O N S  86002 (3)	INSP EC T I O N S  86004 (4)	INVEST I G A T I O N S (Hours) 86001 (5)	INVEST I G A T I O N S (Hours) 86004	DOMESTIC S A M P L E C O L L 86001	FIELD E X A M S/ T E S T S 86001 (6)	FIELD E X A M S/ T E S T S 86002 (7)
	TOTAL FIELD	105	5	3	22	658	31	5	75	30
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)								
	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
SE	FORENSIC CHEM. CTR									
	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	REGIONAL LAB									
SW	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
	REGIONAL STAFF									
	DALLAS									
PA	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
	REGIONAL STAFF									
	LOS ANGELES									
SAN FRANCISCO										
SEATTLE										
PACIFIC REGIONAL LABORATORY-SW										
PACIFIC REGIONAL LABORATORY-NW										
HOURS PER OPERATION		17.2	52.4	36.0	20.0			3.0	5.0	4.4
TOTAL HOURS		1806	262	108	440	658	31	15	375	132
CONVERSION FACTOR		950	1180	950	950	950	950	950	950	950
TOTAL OPERATIONAL FTEs		1.90	0.22	0.11	0.46	0.69	0.03	0.02	0.39	0.14

9. Remarks

**Laser products (86001)**  
 1) Inspections should be conducted on manufacturers of Class IIIb and Class IV products. Medical laser systems should be highest priority, followed by industrial, and commercial lasers (including laser light shows) or inspections directed based on a for cause request. For medical lasers, a joint QSIT and electronic product radiation control inspection should be conducted. 2) Number of inspections to be conducted by WEAC Analysts. 5) Investigation Hours--refer to Compliance Program for reporting information. 6) Field tests may be conducted for any laser products located at a user facility, following the same priority scheme as for inspections (Class IIIb or IV medical, industrial and commercial lasers, including laser light show projectors).

**Sunlamps and sunlamp products (86002)**  
 3) Inspectional figures are only for biennial or for cause inspections of manufacturers of sunlamp products (e.g. sunlamps, booths, or beds). Because sunlamp products are also medical devices, a joint QSIT and electronic product radiation control inspection should be conducted. Examination of sunlamp products at a user facility (e.g. tanning parlor, athletic club) are NOT counted as inspections because they are field tests. 7) Each sunlamp product tested may be counted as a separate field test, even if located in a single facility.  
 NOTE: RRHR's Technical Assistance and Coordination under this program is planned under Radiological Health Control Activities (PAC 86008).

**Cabinet x-ray products (86004)**  
 4) Cabinet x-ray manufacturer inspections are to be comprehensive electronic product radiation control inspections. Cabinet x-ray field tests are no longer to be performed routinely under this program. The hours previously associated with field tests have been reprogrammed to inspections.



<b>1. PROGRAM/ASSIGNMENT TITLE</b> Inspections of Manufacturers (Foreign and Domestic) and Field Compliance Testing of Diagnostic X-ray Equipment	<b>2. PPS PROJECT NAME/NUMBER</b> Radiation Control and Health Safety Act (RCHSA) Authority - 86
<b>3. PROGRAM/ASSIGNMENT CODE(S)</b> 86003	<b>4. WORK ALLOCATION PLANNED BY</b> <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER
<b>5. OPERATIONAL FTE POSITIONS</b> 8.6	

R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	1	1	2	1	2	5	5B	9									
		INSPEC- TIONS DOMESTIC  (1)	INSPEC- TIONS FOREIGN  (2)	INSPEC- TIONS DIRECTED  (3)	INVESTI- GATIONS (Hours)  (4)	INSPEC- TIONS  (5)	INVESTI- GATIONS (Hours)  (6)	FIELD EXAMS/ TESTS  (7)	AUDITS  (7)	OTHER OPERATIONS (Hours)  (8)									
	<b>TOTAL FIELD</b>	<b>52</b>	<b>15</b>	<b>5</b>	<b>884</b>	<b>18</b>	<b>1051</b>	<b>345</b>	<b>30</b>	<b>965</b>									
NE	HEADQUARTERS	(b)(2)&(b)(7)(E)																	
	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
WEAC																			
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
SE	FORENSIC CHEM. CTR																		
	REGIONAL STAFF																		
	ATLANTA																		
	FLORIDA																		
	NEW ORLEANS																		
SW	SAN JUAN																		
	REGIONAL LAB																		
	REGIONAL STAFF																		
	DALLAS																		
	DENVER																		
PA	KANSAS CITY																		
	SOUTHWEST IMPORT DISTRICT																		
	REGIONAL LAB																		
	REGIONAL STAFF																		
	LOS ANGELES																		
	SAN FRANCISCO																		
	SEATTLE																		
	PACIFIC REGIONAL LABORATORY-SW																		
	PACIFIC REGIONAL LABORATORY-NW																		
	<b>HOURS PER OPERATION</b>										<b>50.0</b>	<b>85.0</b>	<b>50.0</b>		<b>18.0</b>		<b>3.0</b>	<b>4.0</b>	
	<b>TOTAL HOURS</b>										<b>2600</b>	<b>975</b>	<b>250</b>	<b>884</b>	<b>288</b>	<b>1051</b>	<b>1035</b>	<b>120</b>	<b>965</b>
	<b>CONVERSION FACTOR</b>										<b>950</b>								
	<b>TOTAL OPERATIONAL FTEs</b>										<b>2.74</b>	<b>1.03</b>	<b>0.26</b>	<b>0.93</b>	<b>0.30</b>	<b>1.11</b>	<b>1.09</b>	<b>0.13</b>	<b>1.02</b>

**9. REMARKS**

1) Domestic inspections to be conducted based on the OEI of diagnostic x-ray equipment manufacturers. Joint QSIT and electronic product radiation control inspections should be conducted if possible.

2) Foreign inspections should be joint QSIT and electronic product radiation control inspections if possible.

3) Directed Inspections based on the OEI of diagnostic x-ray equipment manufacturers.

4) Investigation hours for review and planning of activities under columns 1 (Domestic), 2 (Foreign), and 3 (Directed) Inspections.

5) Inspections based on the OEI of diagnostic x-ray equipment assemblers.

6) Investigation hours for review of 2579 forms (reports of assembly) in preparation for performing field tests and field test follow up activities.

7) Field tests and audits are obtained from Attachment A and provided by CDRH's OCER/DMQRP Diagnostic Devices Branch, HFZ-240. Column 5B, Audits, is for quality assurance joint field tests for follow-up tests conducted by an individual qualified as an auditor.

8) Coordination/technical assistance hours for field test activities.

**ATTACHMENT A - 2010 WORKPLAN  
INSPECTIONS OF MANUFACTURERS (FOREIGN AND  
DOMESTIC) AND FIELD COMPLIANCE TESTING  
OF DIAGNOSTIC X-RAY EQUIPMENT**

**NEW ENGLAND DISTRICT**

<b>State</b>	<b>Number Systems Installed</b>	<b>FDA Tests</b>	<b>FDA F/U</b>	<b>Audits</b>
CT	(b)(2)&(b)(7)(E)			
ME				
MA				
NH				
RI				
VT				
<b>Total</b>				

**NEW YORK DISTRICT**

<b>State</b>	<b>Number Systems Installed</b>	<b>FDA Tests</b>	<b>FDA F/U</b>	<b>Audits</b>
NY	(b)(2)&(b)(7)(E)			

**BALTIMORE DISTRICT**

<b>State</b>	<b>Number Systems Installed</b>	<b>FDA Tests</b>	<b>FDA F/U</b>	<b>Audits</b>
DC	(b)(2)&(b)(7)(E)			
MD				
VA				
WV				
<b>Total</b>				

**CHICAGO DISTRICT**

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
IL	(b)(2)&(b)(7)(E)			

**CINCINNATI DISTRICT**

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
KY	(b)(2)&(b)(7)(E)			
OH				
<b>Total</b>				

**DETROIT DISTRICT**

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
IN	(b)(2)&(b)(7)(E)			
MI				
<b>Total</b>				

**MINNEAPOLIS DISTRICT**

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
MN	(b)(2)&(b)(7)(E)			
ND				
SD				
WI				
<b>Total</b>				

**NEW JERSEY DISTRICT**

State	Number	FDA	FDA	Audits
	Systems Installed			
NJ	(b)(2)&(b)(7)(E)			

**PHILADELPHIA DISTRICT**

State	Number	FDA	FDA	Audits
	Systems Installed			
DE	(b)(2)&(b)(7)(E)			
PA				
Total				

**ATLANTA DISTRICT**

State	Number	FDA	FDA	Audits
	Systems Installed			
GA	(b)(2)&(b)(7)(E)			
NC				
SC				
Total				

**FLORIDA DISTRICT**

State	Number	FDA	FDA	Audits
	Systems Installed			
FL	(b)(2)&(b)(7)(E)			

**NEW ORLEANS DISTRICT**

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
AL	(b)(2)&(b)(7)(E)			
LA				
MS				
TN				
<b>Total</b>				

**SAN JUAN DISTRICT**

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
PR	(b)(2)&(b)(7)(E)			

**SW REGIONAL STAFF (STATES IN DALLAS DISTRICT)**

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
AR	(b)(2)&(b)(7)(E)			
OK				
TX				
<b>Total</b>				

**SW REGIONAL STAFF (STATES IN DENVER DISTRICT)**

State	Number Systems Installed	FDA Tests	FDA F/U	Audits
CO	(b)(2)&(b)(7)(E)			
NM				
UT				
WY				
<b>Total</b>				

**SW REGIONAL STAFF (STATES IN KANSAS CITY DISTRICT)**

State	Number			
	Systems Installed	FDA Tests	FDA F/U	Audits
IA	(b)(2)&(b)(7)(E)			
KS				
NE				
MO				
<b>Total</b>				

**LOS ANGELES DISTRICT**

State	Number			
	Systems Installed	FDA Tests	FDA F/U	Audits
AZ	(b)(2)&(b)(7)(E)			
CA				
<b>Total</b>				

**SAN FRANCISCO DISTRICT**

State	Number			
	Systems Installed	FDA Tests	FDA F/U	Audits
CA	(b)(2)&(b)(7)(E)			
HI				
NV				
<b>Total</b>				

**SEATTLE DISTRICT**

State	Number			
	Systems Installed	FDA Tests	FDA F/U	Audits
AK	(b)(2)&(b)(7)(E)			
ID				
MT				
OR				
WA				
<b>Total</b>				

1 PROGRAM/ASSIGNMENT TITLE Compliance Testing of Electronic Products at WEAC				2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86															
3 PROGRAM/ASSIGNMENT CODE(S) 86006 A,B,D,E			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 3.9												
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY	1	7	7	7	7	7												
		FOREIGN INSPECTIONS (PL 90-602 STANDARD)	DOMESTIC SAMPLES TO BE ANALYZED MICROWAVE	DOMESTIC SAMPLES TO BE ANALYZED TV - IONIZING	DOMESTIC SAMPLES TO BE ANALYZED X-RAY WHOLE	DOMESTIC SAMPLES TO BE ANALYZED NON-MEDICAL LASERS	DOMESTIC SAMPLES TO BE ANALYZED SUN LAMPS												
	TOTAL FIELD	13	100	3	3	18	10												
	HEADQUARTERS	(b)(2)&(b)(7)(E)																	
NE	REGIONAL STAFF																		
	NEW ENGLAND																		
	NEW YORK																		
	REGIONAL LAB																		
	WEAC																		
CE	REGIONAL STAFF																		
	BALTIMORE																		
	CHICAGO																		
	CINCINNATI																		
	DETROIT																		
	MINNEAPOLIS																		
	NEW JERSEY																		
	PHILADELPHIA																		
FORENSIC CHEM. CTR																			
SE	REGIONAL STAFF																		
	ATLANTA																		
	FLORIDA																		
	NEW ORLEANS																		
	SAN JUAN																		
SW	REGIONAL LAB																		
	REGIONAL STAFF																		
	DALLAS																		
	DENVER																		
	KANSAS CITY																		
PA	SOUTHWEST IMPORT DISTRICT																		
	REGIONAL LAB																		
	REGIONAL STAFF																		
	LOS ANGELES																		
	SAN FRANCISCO																		
SEATTLE																			
PACIFIC REGIONAL LABORATORY-SW																			
PACIFIC REGIONAL LABORATORY-NW																			
HOURS PER OPERATION											70.0	18.0	39.0	421.0	15.0	25.0			
TOTAL HOURS											910	1800	117	1283	270	250			
CONVERSION FACTOR											1180	1180	1180	1180	1180	1180			
TOTAL OPERATIONAL FTEs											0.77	1.53	0.10	1.07	0.23	0.21			
9. REMARKS																			
Workplan includes both foreign inspection and laboratory testing activities for electronic products.																			
(b)(2)&(b)(7)(E) For any inspections of radiation-emitting medical device manufacturers, a joint QSIT and electronic product radiation control inspection should be conducted by a trained investigator. Instructions for performing inspections are provided in Compliance Program 7386.001, with time reported under PAC 86006.																			
Report time for specific lab analyses under PAC 86006, using the appropriate column and an accurate description of the type of product tested (e.g. hand-held laser product, mobile diagnostic x-ray system, household microwave oven) in FACTS.																			

1. PROGRAM/ASSIGNMENT TITLE Imported Electronic Products			2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86						
3. PROGRAM/ASSIGNMENT CODE(S) 86007, 86R824, 86R833, 99R833			4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER				5. OPERATIONAL FTE POSITIONS 7.5		
R E G I O N	6 DISTRICT/ SPECIALIZED LABORATORY		2	2	4				
			ENTRY REVIEW (Hours)	IMPORT INV HOURS	IMPORT FIELD EXAMS				
	TOTAL FIELD		6878	1401	400				
NE	HEADQUARTERS		(b)(2)&(b)(7)(E)						
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB WEAC								
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA FORENSIC CHEM. CTR								
SE	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
	SAN JUAN REGIONAL LAB								
SW	REGIONAL STAFF								
	DALLAS								
	DENVER								
	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT REGIONAL LAB								
PA	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
	PACIFIC REGIONAL LABORATORY-SW PACIFIC REGIONAL LABORATORY-NW								
HOURS PER OPERATION					0.7				
TOTAL HOURS			6878	1401	280				
CONVERSION FACTOR			1200	950	950				
TOTAL OPERATIONAL FTEs			5.73	1.47	0.28				
9. REMARKS									
* Import investigation hours are for field exams (non-Congressional Target), filer evaluations, follow-up to refusals, label exams, and other operations as required by the District to cover program priorities. Districts should report time under the appropriate operation and PAC for the activities performed. Field Exams to meet Congressional Targets are planned in a separate column.									
<b>Reporting Guidance:</b>									
- Import Entry Reviews (Electronic and Manual—operation code 14, PAC 86R833);									
- Filer Evaluations (operation code 95, PAC 99R833); and									
- Follow-up to Refusals (PAC 86R824).									

1. PROGRAM/ASSIGNMENT TITLE Radiological Health Control Activities				2. PPS PROJECT NAME/NUMBER Radiation Control and Health Safety Act (RCHSA) Authority - 86					
3. PROGRAM/ASSIGNMENT CODE(S) 86008, 86009			4. WORK ALLOCATION PLANNED BY <input type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER			5. OPERATIONAL FTE POSITIONS 5.0			
R E G I O N	6. DISTRICT/ SPECIALIZED LABORATORY					8 MISC (Hours) RRHR 86008	9 TECHNICAL ASSISTANCE (Hours) RRHR 86009		
	TOTAL FIELD					3600	2400		
NE	HEADQUARTERS					(b)(2)&(b)(7)(E)			
	REGIONAL STAFF								
	NEW ENGLAND								
	NEW YORK								
	REGIONAL LAB								
WEAC									
CE	REGIONAL STAFF								
	BALTIMORE								
	CHICAGO								
	CINCINNATI								
	DETROIT								
	MINNEAPOLIS								
	NEW JERSEY								
	PHILADELPHIA								
SE	FORENSIC CHEM. CTR								
	REGIONAL STAFF								
	ATLANTA								
	FLORIDA								
	NEW ORLEANS								
SW	SAN JUAN								
	REGIONAL LAB								
	REGIONAL STAFF								
	DALLAS								
	DENVER								
PA	KANSAS CITY								
	SOUTHWEST IMPORT DISTRICT								
	REGIONAL LAB								
	REGIONAL STAFF								
	LOS ANGELES								
	SAN FRANCISCO								
	SEATTLE								
HOURS PER OPERATION									
TOTAL HOURS								3600	2400
CONVERSION FACTOR								1200	1200
TOTAL OPERATIONAL FTEs								3.00	2.00
9. REMARKS See Continuation Sheet for footnotes, guidance, etc.									

## CONTINUATION SHEET

1. PROGRAM/ASSIGNMENT TITLE

Radiological Health Control Activities

2. PPS PROJECT NAME/NUMBER

Radiation Control and Health Safety Act (RCHSA)  
Authority - 86

y. Remarks

**FOOTNOTES FOR MEDICAL DEVICE AND RAD HEALTH USE CONTROL & POLICY IMPLEMENTATION ACTIVITIES (86008):**

\* RRHR time for CDRH programs is planned under this program, the Emergency Response and Planning Activities program, and the Mammography Facilities Inspection Program; 1200 hours will be shown in Mammography. A portion of this total block of time per RRHR position includes Federal/State liaison activities and use consultation to conduct this program.

This block of time also includes coordination, technical assistance, and other activities performed by RRHRs under the following programs:

- Field Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended (PAC 86002);
- Field Compliance Testing of Diagnostic X-Ray Equipment (PAC 86003);
- Field Compliance Testing of Cabinet X-Ray Equipment (PAC 86004);
- Medical Device and Radiological Health Use Control and Policy Implementation (PAC 86008);
- Emergency Planning and Response Activities (PAC 86009);

**Any time in excess of 0.5 hours used for these programs should be reported into FACTS against the applicable PAC.**

**FOOTNOTES FOR EMERGENCY PLANNING AND RESPONSE ACTIVITIES (86009):**

Technical Assistance hours will be performed by RRHRs.

Program activities include: providing technical assistance to state and local agencies regarding emergency response planning; reviewing and evaluating emergency plans related to nuclear power plants.